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PERSPECTIVE ON PATENTS: HARMONIZATION AND OTHER MATTERS

HEARING

BEFORE THE

SUBCOMMITTEE ON INTELLECTUAL PROPERTY

OF THE

COMMITTEE ON THE JUDICIARY

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CONTENTS

STATEMENTS OF COMMITTEE MEMBERS

WITNESSES

SUBMISSIONS FOR THE RECORD

PERSPECTIVE ON PATENTS: HARMONIZATION AND OTHER MATTERS

TUESDAY, JULY 26, 2005

UNITED STATES SENATE,
SUBCOMMITTEE ON INTELLECTUAL PROPERTY, OF THE
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Subcommittee met, pursuant to notice, at 2:37 p.m., in room SD–226, Dirksen Senate Office Building, Hon. Orrin G. Hatch, Chairman of the Subcommittee, presiding.

Present: Senator Hatch.

OPENING STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM THE STATE OF UTAH

Chairman HATCH. Good afternoon. Welcome to today's hearing on patent reform.

Today we are going to focus principally on an important group of issues in the patent reform debate surrounding the proposals to increase harmonization in patent law and practice in the United States with prevailing international norms. I am pleased to note that we have really a great, top-notch panel of experts to inform our views about this highly technical area or set of areas of patent reform.

We are a little bit pressed for time today because there is another important hearing in this room at 4 o'clock, so I will try and keep my remarks brief.

Over the past several decades various experts, including academics, presidential commissions and blue-ribbon panels, have advocated increased harmonization between the U.S. patent system and the patent systems of other countries.

Advocates of harmonization often site three different types of anticipated benefits from increased harmonization: first, faster, more predictable patentability determinations; second, decreased litigation costs in the long term; and third, reduced redundancy in patent examination and associated decreases in cost to patent holders in obtaining global patent protection.

However, there are those who question the need for increased harmonization or who oppose it outright on a variety of bases. Some argue that harmonization would disadvantage specific interests or groups including independent inventors, small businesses, nonprofit entities and educational institutions. Others argue that the potential efficiencies of harmonization simply do not outweigh the perceived benefits of some of the unique aspects of patent law.

I hope that today's hearing will shed some light on these and other issues that are central to the current patent reform debate. In particular, I hope that it will clarify some of the arguments from multiple perspectives regarding moving from our traditional first-to-invent regime to the internationally adopted first-to-file system, eliminating the best mode requirement, requiring publication of all patent applications after 18 months, and moving toward a more uniform definition of prior art that is closer to what is used internationally.

I also suspect that today's panelists may have some comments on other aspects of patent reform proposals that are circulating on Capitol Hill, and we would be interested in hearing about that as well.

I want to note that we have endeavored to achieve a balance between diversity of viewpoints and expertise on this panel, but of course, not all affected parties can testify today, so in the interest of compiling a complete public record on these issues, we invite other interested parties and organizations to submit written statements for the record.

Senator Leahy is at an appropriations meeting, and he may or may not be able to arrive, but when he does we will certainly recognize him for any remarks he would care to make.

As I mentioned, we are lucky to have such a truly amazing and outstanding panel of witnesses with us today. First we are going to hear from an old friend, Gerald J. Mossinghoff, former Assistant Secretary of Commerce and Commissioner of Patents and Trademarks. Mr. Mossinghoff is currently Senior Counsel at Oblon, Spivak, McClelland, Maier & Neustadt, where he continues to focus on patent issues for a wide variety of clients.

Next we will hear from Q. Todd Dickinson, Former Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office. Mr. Dickinson—and we welcome all of you here—is now Vice President and Chief Intellectual Property Counsel at GE.

After Mr. Dickinson is Marshall C. Phelps, who is Corporate Vice President and Deputy General Counsel for Intellectual Property at Microsoft.

Next we will have Christine J. Siwik. I think I am pronouncing that right, Christine. Is that okay? Okay. Outside Counsel for Barr Laboratories, the company she is representing here today, or at least that viewpoint.

Following that we will hear from Charles E. Phelps, Provost of the University of Rochester—we are very grateful to have all of you here—who is representing the Association of American Universities at this hearing.

And last but not least, we have David Beier, Senior Vice President of Global Governmental Affairs at Amgen. While I suspect Mr. Beier remains a committed Democrat, I still have hopes that he will someday see the light.

[Laughter.]

Chairman HATCH. I have been working on him. He has always been a great witness for this Committee and has always helped me in every way to hopefully do a better job.

I want to thank you all for being here today. I really look forward to this testimony. Because of the time constraints today I may be a little stricter than usual in limiting opening statements to 5 minutes. I would ask that all witnesses attempt to wrap up their statements when the yellow light shows on this little thing in front of you, when that yellow light comes on, so that we will have enough time for as many statements and questions and as much dialogue as possible.

I also want to commend our colleagues over in the House, Chairman Lamar Smith and ranking Democratic member, Howard Berman. They have done an awful lot of hard work in moving patent reform in the House, and Senator Leahy and I will continue to work with them and other interested parties. We are very interested in getting some work done that basically is correct, does the best job we can for the overall processes that we are all concerned about here.

So with that, Mr. Mossinghoff, we will turn to you.

STATEMENT OF GERALD J. MOSSINGHOFF, FORMER ASSISTANT SECRETARY OF COMMERCE AND COMMISSIONER OF PATENTS AND TRADEMARKS, AND SENIOR COUNSEL, OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C., ALEXANDRIA, VIRGINIA

Mr. MOSSINGHOFF. Thank you, Mr. Chairman. It is a great honor for me to appear before the Subcommittee today to discuss international patent harmonization, an area that I have worked at for a long time as you know.

In the interest of time I am going to move to page 3 in my statement, and point to Figure 1 that is on page 3. That is an analysis done by the Japan Patent Office of the cross-border flow of patent applications among Japan, Europe and the United States last year. You see a total of 210,000 applications flown across the borders, separating those three trilateral barriers.

A total of more than 940,000 applications were filed last year in the European Patent Office, the U.S. Patent and trademark Office and Japan Patent Office, 940,000. It is going to be a blink of an eye till that gets up to a million applications filed each year in those three offices. We really do need to move to deep harmonization and work sharing if we are going to do a decent job of examining that one million number of applications filed each year.

An initial effort to achieve deep harmonization of patent laws within the World Intellectual Property Organization was cut short in 1997 when then Secretary of Commerce, the Ronald H. Brown, informed the WIPO that while "international negotiations continue, [the United States] will maintain our first-to-invent system, while keeping open the option of full harmonization in the future."

Recent efforts of the World Intellectual Property Organization's Standing Committee on Patent Law, working on a substantive patent law treaty, have not fared much better, largely as a result of a few developing countries trying to use that forum to roll back the progress that we made in the landmark TRIPS agreement.

Currently, the hopes for substantive patent harmonization hinge on the efforts of a number of countries that signed a statement of intent of interested countries. They met in Alexandria in February,

and April in Europe, and they are going to meet again in JPO, the Japan Patent Office, and the USPTO.

I have attached to my statement an article I wrote some time ago about what a world patent system might look like, and I would appreciate that being put in the record of these hearings.

Chairman HATCH. Without objection we will do that.

Mr. MOSSINGHOFF. Although there are many aspects of deep patent harmonization, none is more important than the United States moving to a first-inventor-to-file system of priority. At the end of 1997 there were two nations that used the so-called first-to-invent system, the United States and the Philippines. Effective January 1, 1998, under its Republic Act No. 82–93, the Philippines adopted a first-to-file system, leaving the United States alone in the world with a first-to-invent system.

An argument is sometimes heard that adopting the universal first-inventor-to-file rule, would somehow disadvantage independent and small businesses, two classes of extremely important and productive users of the U.S. patent system. 22 years of experience indicates that that is not the case; actually, the opposite is true. Small entities were disadvantaged more often than they were advantaged by the first-to-invent system.

As you recall, Mr. Chairman—it is a long time ago, but it is still very important—you introduced a bill in the Senate under President Reagan's administration to greatly increase user fees and to let the Patent Office use those user fees to run its operations rather than having them go into miscellaneous receipts of the Treasury. That bill was enacted in Public Law 97–247.

A key part of the statutory scheme, which we recommended and you went along with, was that we would give a 50 percent discount to independent inventors, small businesses and nonprofit institutions, and that is happening today and has happened for the last 22 years in the U.S. Patent and Trademark Office. As a result of that, the applications now have earmarks on them. We know what applications came from independent inventors, what came from small business and what came from nonprofits and what came from large concerns. So for the first time in 1983 we have earmarks on each application. Thus, for the first time the Patent and Trademark Office can tell what happened to them in interferences.

Turning very quickly to page 9 of my statement, of those advantaged by the first-to-invent system, there was 296 small entities, 289 were disadvantaged, a virtual tie. For nonprofit institutions it was 50 to 30; for small businesses, 97 to 92; and then for independent inventors, some of those most vocally in favor of first-to-invent, 139 were advantaged—on page 10—and 167 were disadvantaged. Two things about that, one it is extremely small numbers, but during that period of time we have 4–1/2 million applications, 2–1/2 million patents, and we are talking about whether 139 were advantaged and 167 were disadvantaged. But basically on net, independent inventors did not do as well as they would have under a first-to-file system during our 22 years when we have earmarks on the applications.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Mossinghoff appears as a submission for the record.]

Chairman HATCH. Thank you, Mr. Mossinghoff. We appreciate that.

Mr. Dickinson?

STATEMENT OF Q. TODD DICKINSON, FORMER UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE U.S. PATENT AND TRADEMARK OFFICE, AND VICE PRESIDENT AND CHIEF INTELLECTUAL PROPERTY COUNSEL, GENERAL ELECTRIC COMPANY, FAIRFIELD, CONNECTICUT

Mr. DICKINSON. Thank you, Mr. Chairman. I join my good friend and colleague, Commissioner Mossinghoff, in thanking you and the Committee for hearing from us today. Although we have different political backgrounds, Commissioner Mossinghoff and I are very much aligned on a number of these issues, and particularly on the great need for harmonization, which these hearings seek to address today.

I enjoyed working with you and your colleagues and your staff in the past, particularly on the American Inventor's Protection Act of 1999, and look forward to working together on harmonization and the patent reform efforts which may help implement that.

I am now at General Electric, and we probably have one of, if not the, broadest intellectual property portfolio almost of any other company. It is often said that we are the only company that may have won both a Nobel prize and an Academy Award. This gives us kind of an interesting and maybe a little bit of a unique position on a number of these issues, but in the area of harmonization and international harmonization, as Commissioner Mossinghoff said, this is one of our most important priorities. The breadth of these technologies and the need to protect them around the world, makes this an urgent issue for us. It is also an urgent issue I saw as Commissioner as well, helped negotiate a number of treaties and participated in a number of international organizations. I continue to do so as the American Bar Association's IP Sections Representative to the WIPO.

The challenge right at the moment for international patent harmonization is that we are stuck basically at the WIPO, and there are a few reasons for that. But partly, and candidly, I think it is because there is not a general desire and there is not a sufficient incentive for the bodies to move collectively forward, and so something needs to be done. One of the issues we have talked about, Commissioner Mossinghoff addressed and I will too, the first-inventor-to-file I think is a good faith effort to move that forward.

The impact of international harmonization on a company like mine is enormous. We spend something like $26 million a year maintaining our patent portfolio around the world, and a huge piece of that is a function of the redundancies in the system.

Before I delve into that, I think I should for the record, as we almost always do, touch on another issue that both the recent NAS and FTC reports highlighted, and that is giving the USPTO the resources it needs to perform its critical job. Harmonization will not mean anything if the USPTO does not have the resources that it needs, and while the administration and the Congress ought to be commended for in this fiscal year stopping the fee diversion that

has occurred in the past, we need to end it permanently. If we get those resources let me suggest that one area we should focus some attention is using those resources for additional examination time.

Turning back to harmonization, the key question in large part, as Commissioner Mossinghoff has mentioned, is the priority question, the question of whether we grant priority to the first inventor, as we do alone, or the first inventor to file. The study which Commissioner Mossinghoff cites, a ground-breaking study, clearly shows that the process we use for determining priority is a failed promise for small inventors, even though they are the organization or the collective group which feels most impacted, or believes they are most impacted by this change. No one is more sympathetic to independent inventors than I am. I established the Office of Independent Inventor Programming when I was Commissioner. I outreached to them in every way possible. So I think I understand their concerns, but we need to get, and probably do a better job at educating them about how those concerns are not being met by the current system.

I had the opportunity, when I was Director, to speak to a lot of small inventors. One day a woman from North Carolina came up to me, and she had invented a new soccer net for the children to practice with, and she was complaining, she said, because in Poland she understands people were copying that net and she was not getting anything for her invention, and that was unfair and why could we not do something about that? I had to explain to her patiently that the systems are territorial and that without an international harmonized system, her ability to protect her invention worldwide, even as a small inventor, is severely, severely compromised.

One criticism of the first-inventor-to-file system is that somehow inventors may disclose their invention, someone else may find out something about it through a publication or otherwise, and race to the patent office ahead of them and file the application. They would not be the first inventor though, that is why we call this first-inventor-to-file. They would be a deriver or, frankly, a thief, and we have a mechanism that has been proposed in various legislation that is currently pending, which would deal with that question of determining inventorship in an efficient and effective manner, that would cure this problem, which is probably the leading problem.

The other issue that is very important I think that links to this is grace period. We need to make sure that we maintain the grace period in the United States and that we need to build in incentives to cause other countries like Japan and the European Patent Convention to also put in place a grace period.

You touched on some of the other important harmonization issues, eliminating best mode, permitting the filing in the name of the assignee, publishing all patent applications. Those are very critical.

Post-grant review, which we do not have time to talk about now, is another key area which I know other witnesses will address, which we are very, very supportive of.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Dickinson appears as a submission for the record.]

Chairman HATCH. Thank you.

Mr. Phelps?

STATEMENT OF MARSHALL C. PHELPS, JR., CORPORATE VICE PRESIDENT AND DEPUTY GENERAL COUNSEL FOR INTELLECTUAL PROPERTY, MICROSOFT CORPORATION, REDMOND, WASHINGTON

Mr. MARSHALL PHELPS. Chairman Hatch, I want to thank you for the opportunity to be here today.

Microsoft believes that our patent system is fundamentally strong, but its long-term health requires we take this opportunity to embrace reforms for the 21st century challenges ahead of us. Through its recent hearings on the opportunities to improve it, the Subcommittee has heard testimony on patent quality, the impact of excessive litigation and the benefits of promoting international harmonization. I will talk about all 3 briefly.

Microsoft is among the Nation's largest investors in R&D spending, about $7 billion a year. This makes us one of the Nation's largest holders of IP rights and one of its leading patent filers. Indeed, we are a major customer of the system.

Patents are a key part of our IP portfolio and that of virtually every technology company. The reasons for this are simple. Because patents provide critical protection for distinctive technologies, they encourage technology developers to license and share their technologies, and they provide a repository of accumulated knowledge. Like many companies in the IT sector, Microsoft earns more than 50 percent of its revenues overseas.

While our business and that of a growing number of American companies big and small is global, there is not a global patent system. Inventors who desire protection in a particular country must seek to obtain protection in that country. A focus on promoting international harmonization and greater cooperation at work sharing among national patent authorities is key to reducing these barriers.

It is essential that the U.S. recognize where its system is out of step. As you just heard, the United States is the only country that applies a first-to-invent standard for establishing priority. Every other country awards the patent to the first-inventor-to-file. In the past some have argued that this first-to-invent system benefits small inventors and should be preserved. You just heard about some recent research, and if we have questions on that, I think Commissioner Mossinghoff would be the best one to address that briefly.

As we move to the first-inventor-to-file system, care must be taken to avoid unnecessary changes that would impact patent quality. For example, wholesale redefinition of what constitutes prior art is not required in our opinion for harmonization with a worldwide first-inventor-to-file system, and could serve to increase uncertainty.

We also endorse USPTO publication 18 months after initial filing. The law already requires this where the invention is also the subject of a foreign patent application.

We believe continued adequate funding for the agency and an end to the diversion of user fees paid to the USPTO must be a priority. In fact, if you ask me what one thing we could do, it would be that.

We also believe persistent concerns about patent quality could be mitigated if interested parties were given sufficient opportunity to address questionable patents through appropriate and carefully structured administrative mechanisms. Currently the primary way to challenge the validity of a patent is through litigation. Well, patent litigation is expensive, time consuming and unpredictable. We support the establishment of a post-grant opposition procedure to enable third parties to challenge the validity of issued patents, and we also support proposals to ensure that interested parties have sufficient opportunity to alert the USPTO of questionable patents within the review process itself.

Finally, the IT industry, like so many others, is encountering the enormous cost of dealing with patents of questionable quality. Today hundreds of patent infringement cases are pending against computer software and hardware companies, costing the industry hundreds of millions of dollars each year.

Too many of these cases are brought by speculators who do not develop, make or distribute anything. Our industry is particularly vulnerable to such claims because our complex products often have hundreds of patent or patentable features contained in them.

Patent reform that deals only with the harmonization issue or only with administrative procedures of the PTO ignore the legacy problems associated with the system's weaknesses. In urging that litigation excesses be addressed, we recognize that other industries are not as directly impacted by speculators and others who would abuse the system. We have been working with affected interests to explore ways to address the challenges of excessive litigation, while ensuring that the patent system continues to function well and fairly for all sectors, and we continue to engage in those discussions.

Thank you again for the opportunity for Microsoft to testify today.

[The prepared statement of Mr. Marshall Phelps appears as a submission for the record.]

Chairman HATCH. Thank you, Mr. Phelps.

Ms. Siwik.

STATEMENT OF CHRISTINE J. SIWIK, PARTNER, RAKOCZY MOLINO MAZZOCHI SIWIK, LLP, ON BEHALF OF BARR LABORATORIES, INC., CHICAGO, ILLINOIS

Ms. SIWIK. Thank you, Mr. Chairman. I am pleased to testify today on behalf of Barr Laboratories, the first member of the generic industry invited to express its views on these important patent-related issues.

For the generic industry there is always one paramount question when considering the relative merits of various patent reform proposals: will the legislation have negative, albeit unintended, consequences on successful Federal statutes, specifically the Hatch-Waxman Act of 1984?

As you know, Mr. Chairman, the Hatch-Waxman Act largely is responsible for the robust generic industry that we see today. In its 20 plus years of existence, your legislation has saved the taxpayers and consumers literally tens of billions of dollars. It is in fact an essential component of our health care system, and several critical Federal programs depend on and require the savings that flow from swift generic market entry.

Unfortunately, many of the patent reform proposals currently under consideration, including some proposed in the name of harmonization, threaten to undermine these savings. Indeed, these proposals could jeopardize Congress's ability to finance existing programs such as the MMA's prescription drug benefit which is set to being in 2006, as well as additional programs Congress is considering.

Let me give you an example. H.R. 2795, the legislation being discussed in the House, would eliminate unenforceability as an independent defense to patent infringement. Enactment of this provision would reward fraud before the PTO with a Government-sanctioned patent monopoly. Today a valid patent can be rendered unenforceable because of the patentee's misconduct during the patent application process. But under the proposed House bill, an applicant could be caught in an outright lie to the PTO and continue to reap the benefits of a patent monopoly.

In some industries unenforceable patents might not have a big impact on the consumer, but in the pharmaceutical industry they can cost the public billions of dollars. For instance, a series of patents once protected the drug product OxyContin from generic competition. However, the Federal Circuit recently upheld a decision finding those patents to be unenforceable in light of the material misrepresentations that the patentee made with an intent to deceive the PTO.

If H.R. 2795 was a law of the land today, despite that misconduct finding, that company could continue to generate sales in excess of $2 billion a year through the year 2013 when the last of its patents would expire, and this does not include the 5 plus billion dollars in sales that that company reaped while the litigation itself was pending.

It is hard to see how this result would square with the goals of one of the most successful components of the Hatch-Waxman Act, encouraging generic pharmaceutical companies to challenge the invalid and unenforceable patents that often block introduction of less expensive generic drugs.

Another problematic provision in H.R. 2795 that I would like to briefly mention today is the proposed elimination of the best mode requirement currently found in Section 112 of the Patent Act. The patent law strikes a bargain. In the pharmaceutical context that means that the public suffers monopoly prices for medicines for a limited period of time in exchange for the patentee's complete disclosure of the claimed invention and the right of generic companies to use that invention once the patent expires. Without the best mode requirement, a patentee continues to get exclusivity while actively concealing the best way to carry out its invention. The bargain no longer exists, leaving the public with the short end of the stick.

At the same time that Congress is considering such counterproductive proposals, abuses of the patent system go unaddressed. In Barr's experience, many of the patents that brand companies obtain seem to have more to do with inventive legal strategies than with true scientific innovation. For example, on a single product that Barr currently is pursuing, the brand company has amassed over 200 patents which would provide that company with roughly four decades of patent production.

From Barr's perspective, addressing this kind of manipulation of the patent system would have at least two obvious benefits to the public. First, it would help ensure that consumers continue to enjoy the much-needed benefits of Hatch-Waxman, one of the most important consumer protection bills ever passed by Congress. Second, it would help lighten the load of an already beleaguered Patent Office, which must contend with applications that all too often the pharmaceutical arena reflect little if any technological advancement.

Again, Mr. Chairman, thank you very much for the opportunity to testify. As I stated at the outset of my remarks, Barr believes it is imperative that Congress carefully scrutinize any patent reform legislation to ensure that it does not create negative consequences for the many people who rely on Hatch-Waxman's continued success.

I would be happy to answer any questions that the Committee might have.

[The prepared statement of Ms. Siwik appears as a submission for the record.]

Chairman HATCH. You certainly know how to talk about Hatch-Waxman is all I can say.

[Laughter.]

Chairman HATCH. I am happy to hear all of that.

Mr. Phelps.

STATEMENT OF CHARLES E. PHELPS, PROVOST, UNIVERSITY OF ROCHESTER, ON BEHALF OF THE ASSOCIATION OF AMERICAN UNIVERSITIES, AMERICAN COUNCIL ON EDUCATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES AND COUNCIL ON GOVERNMENTAL RELATIONS, ROCHESTER, NEW YORK

Mr. CHARLES PHELPS. Thank you, Chairman Hatch. I appreciate the opportunity to appear before the Subcommittee to present the views of four associations that represent the universities and medical colleges that conduct most of the Nation's basic research, and whose working group on patent reform I chair.

The research conducted in our Nation's universities expands the frontiers of knowledge and produces discoveries that enhance our Nation's security, strengthen our economic competitive, enrich the lives of our citizens. We believe the landmark 1980 Bayh-Dole Act has been an extraordinarily successful mechanism for facilitating the transfer of university basic research into the commercial sector for development, and of course the patent system is an integral part of this process.

Changing the U.S. patent system from a first-to-invent to a first-inventor-to-file process would harmonize U.S. patent law with that

of other countries, increasing the simplicity and reducing the costs of patent filing, all desirable goals.

Moving to a first-inventor-to-file process would also add greater clarity to the patent system by replacing subjective determination of the first inventor with the objective identification of first filer. This change would reduce or eliminate unpredictable and often substantial costs of interferences and litigations associated with determining the first inventor.

However, other ramifications of moving to a first-inventor-to-file process raise concerns among some members of the university community. Before filing a patent application, universities often need time to consider the potential commercial application of a basic research discovery. Universities also need to assess the receptivity within the commercial sector to licensing any resultant patent for development. Budgetary limitations may limit the resources universities can devote to rapid filing of full developed patent applications.

Despite these concerns, the associations recognize the benefits of a first-inventor-to-file and would not oppose a move to such a process if the U.S. patent law maintains three components of the current law: first, the 12-month grace period for published articles containing a disclosure of the invention; second, provisional applications; and third, the requirement that an applicant sign an oath or a declaration that he or she is an inventor of the claimed invention.

Let me comment briefly more on two of these issues. First the provisional application procedure under which the patent applicant can file a provisional application and obtain an early filing date. This can aid in rapid filing. It will be particularly important to universities operating in a first-inventor-to-file process.

Second, current U.S. patent law provides a broad 12-month grace period before the effective filing date of an invention, during which the publication or other disclosures of the inventor and others carrying out research in the same area are not treated as prior art. This provisions facilitates research collaboration and encourages publication and other forms of disseminating research results. A broad grace period preserves the ability of researchers to decide what to publish, where to publish and when without foreclosing of the opportunity of other researchers in the field to pursue a patent application.

We recognize that in a first-inventor-to-file patent system such a grace period could allow another person to scoop up or at least speed up the work based on an original inventor's publication. But we believe the benefits to research collaboration and open communication encouraged by a broad grace period would override this problem.

The benefits of the grace period should not be limited to the United States. In the spirit of harmonization we urge Congress to request the administration to seek adoption by other countries of the U.S. grace period as recommended by the National Research Council.

My written testimony presents the views of these associations on several other patent reform proposals. I note here briefly our support for post-grant opposition procedures and continuation of the

CREATE Act. I also want to emphasize the importance of the continuation applications for universities, particularly in some fields such as the life sciences. The rapid pace of discovery makes continuation applications, particularly including continuation in part, an important procedure for updating applications to reflect recent developments.

In general the goals of the associations for which I am testifying today would be to support harmonization when possible, find ways to reduce cost and remove ambiguity in the patent system, and I am pleased to answer any questions that might arise later.

Thank you.

[The prepared statement of Mr. Charles Phelps appears as a submission for the record.]

Chairman HATCH. Thank you, Mr. Phelps.

Mr. Beier.

STATEMENT OF DAVID BEIER, SENIOR VICE PRESIDENT FOR GLOBAL GOVERNMENT AFFAIRS, AMGEN, WASHINGTON, D.C.

Mr. BEIER. Chairman Hatch, my name is David Beier.

I am here today representing Amgen, which earlier this year celebrated its 25th birthday. Amgen began as a result of a collaboration between researchers at the University of California Los Angeles and venture capitalists.

In our 25-year history we have produced products as a result of massive investments of billions of dollars that have treated 8 million Americans and people worldwide. The products that we produce, 7 in number that are approved, 7 major products treat anemia associated with dialysis, anemia associated with chemotherapy and rheumatoid arthritis and a number of other grievous illnesses.

The representation here today is on behalf of Amgen, but you should know, and I am sure you do, Mr. Chairman, there are 1,500 biotechnology in the United States. The United States is a leader in biotechnology. The biotech industry currently employs 400,000 Americans. Each of those jobs in turn has a multiplier effect of 5.7 other jobs, and the total market capitalization of the industry has gone from virtually nothing in 1980 to over $300 billion. The industry has produced scores of products that have been approved by the FDA and those products have treated worldwide more than 320 million people.

The reason that the United States is substantially ahead of the rest of the world in biotechnology is through, Mr. Chairman, to be blunt, a lot of your work. It is a product of a science-based economy that has supported basic research at the NIH, a science-based approach to regulation at the FDA, access to venture capital through sound tax rules, and also to be even blunter, the world's best patent system.

We as Amgen are deeply worried that in the rush to change the patent law that we lose focus on the importance of all of the accomplishments of a strong intellectual property system. There are, however, some systems' changes that are appropriate. Therefore we support an end to fee diversion, making sure, as Todd Dickinson noted, that the PTO has adequate funding.

We support increased compensation for examiners especially in hard to recruit examination areas like biotechnology or software. We support changes in rules of litigation which require courts to inquire into the subjective mindset of patent applicants, things like inequitable conduct. And we support changes in the standard of willfulness, which we believe will increase the amount of due diligence that inventors have to engage in before they can avoid liability.

We also support changes in the first-inventor-to-file system along the lines of the testimony of Mr. Mossinghoff and Mr. Dickinson.

We do have two major sets of concerns. The first is with respect to procedures that have been proposed in the House with respect to injunctions. The reason for that opposition is multi-fold. First, to the extent that it includes anything like a working requirement—which, Mr. Chairman, you worked a long time to eliminate in WTO—we think it could be a dangerous precedent in a international context. We are also concerned that it would be inconsistent with legislation that you helped author in 1988 on the Tariff Act changes, eliminating the requirement of proving injury in addition to validity and infringement.

Most importantly, we are concerned that changes in the law of injunctions will fundamentally alter the equation the Supreme Court has upheld many times, which is, intellectual property is property, and that once you have found that it is validly obtained, that the title is settled and it has been infringed, there should be action taken against it and not just damages.

The second set of concerns relates to post-grant opposition procedures. This procedure is known in Europe and it has been frequently used, somewhere between 5 and 9 percent of the time. If that system were in place in the United States, it would choke the Patent and Trademark Office and make it unable to achieve the proponent's goals of security quality. That dilemma is exacerbated of there is a different burden of proof in a post-grant opposition procedure. If you have a lower standard to invalidate a patent, the fear is that more people will rush into a post-grant system and that the goals of the proponents will be undermined.

We are also concerned that the standard in order to get into a post-grant opposition procedure is not high enough, and therefore you have not narrowed the funnel enough to be effective.

In sum, Mr. Chairman, there are many elements of a consensus bill that could go forward that Congress should pass. There are some elements that should be neglected. If not, there a substantial risk if language on injunctions or inappropriate procedures on post grant are included that there will be fewer cures, slower approvals and fewer choices for patients at the end of the day.

Thank you.

[The prepared statement of Mr. Beier appears as a submission for the record.]

Chairman HATCH. Thank you. You have all been very interesting here today. I am extremely interested in every one of your comments. What a wonderful panel this is.

Let me just say, in hopes of generating some discussion on the core feature of many of harmonization proposals, the first-to-file rule. I would like each witness on the panel to expand on what was

said in your opening statements about whether the U.S. should move to a first-to-file system, what are the perceived benefits and detriments of doing so? What are your best arguments from each of your perspectives on both sides of these issues? Mr. Mossinghoff?

Mr. MOSSINGHOFF. Mr. Chairman, I would lead off. For U.S. going to a first-to-file system I believe is something the U.S. ought to do outside of harmonization concerns. I think that as long as we have a so-called first-to-invent system, any discussion of deep harmonization, it becomes hypothetical or theoretical. It is just not going to happen.

Setting that aside, I think first-inventor-to-file makes a lot of sense for everyone. As I have indicated, and the data are pretty clear over the last 22 years that it does not favor independent inventors. To the contrary, it somewhat disfavors them or disadvantages them. It is much simpler. It removes a very complicated set of subjective issues. When did an inventor have a concept of the invention? What kind of proofs can they bring forward? Can they bring corroboration forward?

Interferences, in the patent profession there is a subset called the interference bar, and it is a very, very cumbersome, expensive process to determine under our current rules what is first-to-invent. So I would say first-to-invent is the best practice that we should go to even if there were no concerns of international harmonization. Add the fact that harmonization simply will not occur with our having a system different from the entire rest of the world, that is just a reinforcing reason to go to first-inventor-to-file.

Chairman HATCH. Mr. Dickinson.

Mr. DICKINSON. I probably should just say ditto and sit down. I think Commissioner Mossinghoff has outlined it very, very well. I think in addition to some of the arguments which he made, we have—since the last time when this was thoroughly debated internationally, when the first President Bush—and there was a diplomatic conference at the time—tried to deal with this issues—since that time, a lot of the concerns at the time have been changed by either circumstance or things which we have put in our own law, a provisional patent application, for example, the development of the Internet, which gives the small inventor a lot more access to online searching capability, a lot more online access to legal assistance for the filing of patent applications, and frankly, you can file patent applications online now and search at the USPTO. So the playing field, which was a concern of small inventors, has become a lot more leveled.

In some ways, to be candid, small inventors may actually be slightly advantaged. At a big company like mine we have, unfortunately for good or bad—we try to work on it—we have sometimes cumbersome procedures ourselves to get a potential patent application through our bureaucracy. So I the can be nimble if I need to be, but it is not as easy as it might be for an individual inventor who can make those kinds of decisions to file their application themselves, and can generally do it pretty quickly.

One final point. I think there is a growing consensus. Commissioner Mossinghoff's study in particular was a key in this. There is a growing consensus that this should and is a best practice.

Most recently the House of Delegates of the American Bar Association reversed an over-30-year-old position this past winter, and has now endorsed first-inventor-to-file as a best practice stand alone, exclusive of international harmonization.

Chairman HATCH. Mr. Phelps.

Mr. MARSHALL PHELPS. I would just echo what you have heard. I would say two things. There is no doubt it is a best practice. And there is little doubt in my mind at least, we will not have harmonization without this issue being undertaken.

I guess to the small inventors of the world I would say if we need to do more to make the system accessible to small inventors and work for small inventors, then we ought to do it, and we ought to find ways to make that happen if they are not sufficient already.

I would agree with Todd that we are in a world-is-flat situation here, and I do think that the system is far more accessible than it used to be for all concerned.

Chairman HATCH. Ms. Siwik.

Ms. SIWIK. Mr. Chairman, we obviously understand the points that my fellow panel members have made. But speaking for a generic pharmaceutical company, we see some potential benefits to adopting the first-inventor-to-invent system, including for the generic companies certainty when evaluating what is and is not prior art. However, Barr has not yet seen a proposal implementing that system where the cost to the generic companies outweighs the harm that would be done. H.R. 2795 is an example of such a proposal where the harm that would be done in implementing that system, the harm to generic companies, would far outweigh the benefits that Barr sees to adopting the system at this time.

Chairman HATCH. Mr. Phelps.

Mr. CHARLES PHELPS. Thank you. I would like to put a slightly different cast on the discussion by turning to the primary business of higher education, which is teaching and research. Quite honestly, the current system in the United States is very comfortable for universities in the sense that it provides no impediments at all to open scholarly communication among scholars worldwide. There is no problem in the current system of publishing in advance. It does not harm your ability to file a patent or do anything of that sort.

Under a shift to a first-inventor-to-file system, we can operate under that system reasonably comfortably as long as we have the grace period for publications. The worst outcome for scholarly communication in that world would be one where there is no grace period, because there you have to dampen off all scholarly communication about your work until the patent is filed. It is very inhibiting of appropriate scholarly communication.

The best circumstance would be a very broad grace period such as we currently have, that gives a year's grace both for the publications of the inventor and others from the field, and a narrow grace period that only gives an exception or exemption for publications of the person who is filing for that patent is in between, and that in between or narrow grace period has some perverse incentives in affecting where I would want to publish my work and when and how. There in effect would be a race to get a publication out if you could preempt others from getting a patent, and it might affect the

quality of our scholarly publication in ways that I think would be adverse.

So to me the most important aspect of this is not the shift to first-to-file, which I think we can live with quite comfortably so long as we have that grace period intact, preferably the broadest of all possible grace periods in terms of how much publication it encompasses.

Chairman HATCH. Thank you.

Mr. BEIER. Mr. Chairman, I am just going to focus on one component, that is best mode and the elimination of best mode that was first proposed in 1992 by an advisory Committee under President Bush and has been ratified as a recommendation by the National Academy of Sciences. There is good reason for eliminating best mode separate and apart from harmonization. There is already an enablement requirement, and the only purpose that best mode serves is to permit the courts to inquire into the mental state of the patent applicant, as to whether they knew the best mode at the time of the application. It does not advance in any kind of material way, according to the National Academy, the useful arts and sciences, which is after all the constitutional purpose for the patent law.

Chairman HATCH. Most of all of you today are in agreement that harmonizing the U.S. patent system could benefit U.S. interests, if I have read you all correctly. Ms. Siwik says that while this goal is laudable, implementation could be problematic from the standpoint of the industry she represents, that is, the generic drug industry.

For example, you raise, Ms. Siwik, concerns about the proposal to eliminate the best mode requirement, if I have it correctly, and I think you said that this is part of the tradeoff in being exclusive rights in exchange for the full public disclosure of the invention.

Mr. Beier, if I understood you correctly, you said that is a subjective requirement that is the source of extensive litigation designed to attack the underlying invention, not to promote public disclosure, if I have you correctly.

Let me just start with the two former Patent Commissioners, and then we will go across again, and ask what they have to say about the continuing need for the best mode requirement, and then let everybody else comment right across the board.

Mr. MOSSINGHOFF. Mr. Chairman, I support eliminating the best mode requirement. I think the National Academy and the Federal Trade Commission, focusing on expense in litigation and expense of discovery, it is a purely subjective area. The Patent and Trademark Office examiners rarely, if ever, examine against best mode. They have no way of knowing inside the inventor's mind whether there was a mode different from or better than the mode that is disclosed in the patent application. The rest of the world operates on an objective standard to have you enable someone of ordinary skill in the art to make and use the invention. If the answer is yes, then you have filed a sufficient quid pro quo, a constitutional quid pro quo or whatever their version of that is, so I support eliminating the best mode as an unnecessary subjective issue in the current system.

Chairman HATCH. Mr. Dickinson.

Mr. DICKINSON. I would join Commissioner Mossinghoff in that, and again, would support the elimination of the best mode. It is highly subjective, and in litigation it is almost a trap for the unwary, the benefit of which is minimal.

Speaking to international harmonization, and particularly now at the deliberations at the WIPO on this topic, most of the developed countries would like us to eliminate it because we stand alone again with this requirement, so if we are going to have harmonization this is one thing we should consider eliminating to get that harmonization.

Interestingly, there are developing countries, poor countries, who have talked about having us retain the best mode. And what is their reason for that? Well, because they would like to be able to learn very quickly or learn easily how to make our patented inventions and then use them many times possibly while there are still patents in force, and I think that kind of, shall we say, technology transfer is inappropriate.

Chairman HATCH. Mr. Phelps?

Mr. MARSHALL PHELPS. Not much to add except to say that any time you can eliminate an unnecessary subjective test is probably a good thing, and this is probably one of those good things, at least if you pay attention to the National Academy studies on this, and we would support that.

Chairman HATCH. Ms. Siwik?

Ms. SIWIK. Mr. Chairman, I cannot speak for what the best mode does or does not do in other areas of technology or how it fares from a purely intellectual, theoretical standpoint for debating purposes, but in the pharmaceutical industry the best mode is critical. It is not duplicative of the written description requirement. It is not duplicative of the enablement requirement, and it does not increase the cost of litigation. I have been litigating Hatch-Waxman cases for 10 years. I can scarcely think of a case that I was not litigating where we did not talk with the inventor for one reason or another during deposition. The fact that we asked some questions about whether or not he or she had a subjective best way of carrying out the invention did not appreciably add to the length of deposition, let alone the cost of the litigation.

The best mode in the generic pharmaceutical or pharmaceutical context provides a very different function than enablement or the written description. It tells the public the inventor's best way of carrying out an invention. The inventor should be the most familiar person with the subject matter of that patent, and if he or she has a best way of carrying it out, that is what the public is entitled to under the bargain that the law strikes.

In the pharmaceutical industry the public suffers monopoly prices for years, and the exchange, the benefit they are supposed to get from that is public disclosure sufficient for companies like Barr and other generics to pick up those teachings and use them to develop their own products.

I understand that the best mode can sometimes involve commercially sensitive information, and it is information that companies might not want to share, but that amounts to a trade secret. If someone wants to maintain that information as a trade secret they certainly can, but the patent law should not let them allow trade

secrets by burying the best mode of carrying out the invention and still receiving the monopoly that the Patent Act provides.

Chairman HATCH. Interesting.

Mr. Phelps.

Mr. CHARLES PHELPS. I think the general view of those in higher education would be that removal of subjectivity would be generally desirable, and the best mode certainly falls into that class.

I would also ask the question, as an empirical economist—my training before I became provost—and that is, how often—and I do not know the answer to this, but ask how often would the best mode described in original patent filing still be the best mode at the time the patent had expired and became available for others to use? My conjecture would be that technical progress would make that best mode at original declaration somewhat outmoded, but that is an empirical question in balancing the benefits and cost of that clause.

Mr. BEIER. Mr. Chairman, Provost Phelps is absolutely correct. One of the reasons best mode does not make a lot of sense is the best mode at the time a patent is filed and the best mode at the time the patent is issued is oftentimes different, so it is a trap for the unwary to determine how best mode might change during the patent application process.

There is little doubt, however, that I need to disagree with the witness from the generic drug industry who has used twice the phrase "suffers monopoly prices." All of us up here who have represented inventors and copyright owners have been in a situation where people have attempted to free ride on our inventions. The fact that we have gone through a process of obtaining a patent or a copyright and have the opportunity to exclude others from free riding does not mean monopoly prices, and no one is suffering under the current intellectual property system in the United States. In fact, the reason we have economic growth is we have such a strong intellectual property system.

Chairman HATCH. Let me just say to Mr. Dickinson and Mr. Mossinghoff again, although it is not strictly relevant to most of the harmonization issues, I would like to just raise the issue of patent quality while we have this distinguished panel before us, because some argue that certain practices and the incentive structure at the PTO may negatively affect patent quality, and in particular, some argue that the combination of the compensation system for patent examiners and the time pressure to finish the examination serve to create incentives to allow patents to issue without sufficient scrutiny.

Any witness on the panel will be welcome to comment on this, but I would like to at least ask both Mr. Mossinghoff and Mr. Dickinson and Ms. Siwik, in particular, to give their views on the effect of these types of incentives within the PTO.

And also beyond the specific issue of these incentives, I would be interested in hearing the panel's views on the one or two most important things Congress could do legislatively to increase patent quality if we could.

So I turn to you first, Mr. Mossinghoff.

Mr. MOSSINGHOFF. Thank you, Mr. Chairman. Patent quality is job one at the U.S. Patent and Trademark Office, and those ele-

ments of patent reform that people are talking about that could have an adverse impact on patent quality, I think should be really thought through. Two I would bring to mind. One is in the inequitable conduct area there was a provision in the original House bill that had the office doing several investigations and making determinations on inequitable conduct. I think that would detract from the job one of the Patent Office, which is to examine applications in a quality way.

Secondly, the idea of a post-grant opposition, which I fully support, and in fact wrote an article two or 3 years ago proposing a post-grant review—and I talked about what is being called the second window, that there would be a first time immediately after the grant of a patent, and then there would be when you were challenged by the patent. I have since thought more about and heard a lot of discussion, and I think we ought to move very slowly in that area, because we do not want to take the best examiners who do job one and move them off to the opposition procedure. I think we ought to go very slowly in that area.

In terms of more time, I hypothetically support that, but then I am very alive to the number of applications that are being filed these days. There are 350,000 applications. If a patent is granted six or 7 years after the application is filed, it does not serve any interest, and so the office this year is hiring 900 examiners. That is pretty close to the limit of number of people you can bring in and train and mentor, and so I do not in any way disagree that the examiners could use more time productively, but I would go very carefully because of the fact that if a patent is not granted for six or 7 years, it really is not worth a lot to a large number of industries that rely upon a patent being issued a lot sooner than that. So it is a real tradeoff that you and the policymakers in the Government are going to have to make on how to do that.

Chairman HATCH. Mr. Dickinson.

Mr. DICKINSON. Just to speak to something I spoke to in my testimony and to link it up to some of the things Commissioner Mossinghoff just said, I think the resources that the office needs desperately to do this job is the number one and number two issue with regard to patent quality. It affects everything from top to bottom. It affects the ability to hire more examiners. I also went through a situation where I hired almost 1,000 examiners 1 year when we had raised the additional revenue to allow us to do that, and it was extremely important. This is not throwing money at the problem as it is sometimes characterized. It is a system that desperately needs the additional resources, additional training resources, additional search and examination resources, additional ability to develop and library prior art and gain access to that prior art, a key issue for quality.

Examiner compensation continues to be an issue. I was pleased that during my tenure we were able to increase examiner compensation by around 10 percent 1 year, and I think that is a good thing, and it slowed attrition, which was a major problem at the time. Retaining skilled examiners, who we have a significant investment in, is a key issue for the office.

I may differ just slightly with Commissioner Mossinghoff on the issue of time. I am probably more of a proponent of devoting some of those resources to the issue of time.

With regard to the question of incentives in the current system, I think—Commissioner Mossinghoff may correct me—I think the last time this was reviewed may have been over 20 years ago. A Rand study was done as to how that time gets allocated. It may be that it is time to do that again. I had given some consideration to that. It takes many to do that, so additional resources are needed for that kind of study, but it may be that the time has come to do that.

Chairman HATCH. Ms. Siwik, should we go to you? And then anybody else who cares to comment.

Ms. SIWIK. Mr. Chairman, you are correct that Barr believes that increase patent quality should start in the Patent Office, and this sentiment has obviously been echoed by several people here today and by other witnesses that appeared in the House. Barr, in its written testimony, emphasized the compensation system, and we believe that a balance has to be struck between quick review of patent applications and a quality review of patent applications, that the compensation system cannot just compensate people for saying yes to patent applications, but that they have to say yes to quality patent applications.

The Federal Circuit has recently emphasized that the issuance of invalid patents has extremely detrimental consequences to the public, and in the pharmaceutical context those negative ramifications are huge because the public does get saddled with monopoly prices for drugs. And I understand that the representative from Amgen does not like the term "monopoly prices for drugs," but the fact of the matter is the American public today pays an enormous amount for their health care costs, and that is particularly true in the biologic area where today there is not generic competition.

Chairman HATCH. Okay. Anybody else care to comment?

Mr. BEIER. Mr. Chairman, if I could comment briefly on the proposals that have been made by the other witnesses with respect to post-grant opposition as a cure. I think we need to be modest in our ambitions. Many of the proposals that are before the Committee today go back to recommendations from President Johnson—that is five Presidents ago—including a post-grant procedure. The experience to day in Europe is that it is not a panacea for quality problems. And if you do not have a high hurdle before you can file a post-grant procedure, that is something like a prima facie showing of invalidity, or if you have procedures which encourage people to take advantage of the differences in the burden of proof for invalidating a patent, for example, having a preponderance standard if it is an administrative or quasi-judicial proceeding in the Patent Office and it is clear and convincing evidence in court, you may have more people using post-grant than is appropriate and it may not solve the problems that the proponents really want.

There are ways of attempting to deal with that either through experimentation or the like, but the idea that you can quickly implement a massive program which could potentially involve thousands of cases and substantial cost, probably very, very high user fees, as a solution to quality I think goes in the wrong direction.

The correct direction is that mentioned by Mr. Mossinghoff and Mr. Dickinson, which is to focus on the front end of the funnel to make sure that patent examiners are given the resources, that there is a second eye review of important patents, that the training is adequate and the like, instead of trying to build in a better, bigger filter for allegedly invalidly issued patents.

Mr. MARSHALL PHELPS. Senator, just one quick point. You were asked what Congress can do. I think there are three things. The first thing is much of what comes down in all of this discussion are resources, and that is the whole diversion question, and so if I were to pick one thing that Congress could do it would be to fix the diversion of fees.

I think some of these administrative points—

Chairman HATCH. I am trying to do that.

[Laughter.]

Mr. MARSHALL PHELPS. I know. Whether it is pre-grant submissions or post-grant procedures or whatever you have, clearly we ought to walk before we run, but that does not mean we should not consider them, because I would just add that the worst place to work this stuff out is in the courtroom at the back end of the system, and that is today what we are doing, so I would say anything that at the end of the day results in better patents is a victory for everybody, and I would say let us put the weight behind that arrow at this point.

Chairman HATCH. Okay. Let me—I know I am keeping you too long, but it has been interesting to me. I would like to just chat a little bit about patent trolls, and much has been said about that, where it meant nothing but litigation, I might add. Has anybody on this panel ever met a patent troll?

[Laughter.]

Mr. BEIER. Mr. Chairman, yes.

Chairman HATCH. You have?

Mr. BEIER. Yes. I think you are actually asking the right question.

Chairman HATCH. Is this a big part of the problem? I mean I would like to know, and what is the actual evidence if you can?

Mr. BEIER. Well, I think it is really a definitional question. If the question is, should there be people who obtain patents who have no intention of commercializing them, that is, manufacturing and distributing them, I think the answer is, yes, there should be such people. One of them is sitting next to me representing the university community. Universities are not about the business of making and distributing products. Dean Kamen, who testified before you some weeks ago, by all legitimate definitions of most proponents of patent troll cure legislation, he would be a patent troll. I would submit probably General Electric could be construed as a patent troll because they have patents that they do not—

Chairman HATCH. Are you going to take that?

Mr. DICKINSON. I am going to be forced to agree with him.

Chairman HATCH. I did not ask you. I asked General Electric.

[Laughter.]

Mr. BEIER. So I think the question is not whether you use the nomenclature of troll. The question really is, are there adequate remedies for the perceived misconduct of parties in certain indus-

trial sectors in whether the patent law per se should be changed for all technologies to accommodate those sectoral aberrations, and I think that is the point of differentiation, for example, between ourselves and Microsoft. Microsoft has a valid, legitimate business model. It is quite different. Their turnaround time for their $7 billion of R&D is quite a bit faster. It is not the 15 years, $1.2 billion for product development that the biotechnology industry goes through. And they are going to face different competitors and different pressures.

So when people start talking about trolls, it really is going to have to be sectorially specific, factually specific and then procedurally focused.

Chairman HATCH. I have to let——

Mr. Dickinson you agree that GE is a patent troll?

Mr. DICKINSON. Again, as Mr. Beier pointed out, it is a definitional matter. Thomas Edison, who was the founder of our company was actually accused of being a troll on a panel on this topic not too long ago.

We do indeed own patents which we do not use, but which we license to others. We participate in patent pools, like the MPEG patent pool, for example, so this is in large part, any attempt to do something about the issues that are raised here, the problems that are raised here—and they are genuine—is a definitional one at the start.

There are industries which are more affected by this than others. I think the software industry makes a good case. They have a particular set of problems. The challenge is how we define the remedy here. And the principal remedy that has been proposed to this point, which may be changing, but the principal remedy proposed at this point is to change the injunction system, particularly permanent injunctions, and the challenge there, the big challenge there, the big problem there, is that you lower the value of everybody's patents to deal with what I think is a much more discrete problem, a much more bounded problem than even its proponents would have it.

Yes, predatory patent trolls are a problem, but let us confine the remedy of that problem much more narrowly than something like a broad attack on the permanent injunction system.

Chairman HATCH. This has been a wonderful panel. Let me just say that I am going to submit this question to all of you in writing. I would like you to think about it. You do not have to answer it here today, but I would like to go over it with you.

While today's hearing does not focus on following off-patent biologics, I would like to make a comment on this matter while I have this distinguished panel to see if anyone would like to respond in writing back. I will not take your time today to ask you.

One of the most controversial decisions handed down by the United States Supreme Court last term was the takings case in *Kelo* v. *New London.* The majority opinion in that case relied upon a 1984 precedent, and that was *Ruckelshaus* v. *Monsanto.* It involved a provision of the Federal Insecticide Fungicide and Rodenticide Act under which the EPA could use data including trade secrets submitted by a pioneer pesticide applicant in approv-

ing a subsequent application if—and it is a big if—the subsequent applicant paid just compensation.

Now, the recent *Kelo* decision said that while the *Monsanto* case acknowledged that the, "most direct beneficiaries" were the subsequent applicants, it "found sufficient in Congress's belief that sparing applicants the cost of time-consuming research eliminated a significant barrier to entry in the pesticide market and thereby enhanced competition."

I have been interested in the whole area of off-patent follow on biologics for some time, and in addition to the formidable, but in the minds of many experts surmountable, scientific issues. There will be many challenges relating to intellectual property. This includes the extent or manner to which a pioneer firm's data may be relied upon by the FDA, and the competitor firms. There is much to be explored here in my opinion.

The full Judiciary Committee held a hearing on this matter last summer. Now, as we consider this issue, I believe that we should keep it advisable to keep I mind the balance nature of the original 1984 Drug Price Competition and Patent Term Restoration Act, which is called the Hatch-Waxman Bill, and consider trying to design a balanced set of incentives so that both generic and pioneer firms receive, and can do what they actually do best to provide innovative, cost effective products to the American public.

The Subcommittee is going to examine these issues further in the future, but I thought that I would bring to your attention the way the Supreme Court analyzed the *Monsanto* case in the most recent takings decision in *Kelo*.

If you can, if you would take some time and answer that for me, I would be very grateful. I do not expect you to answer that here today, but I would like to have your best feelings on that matter just for the record because it is something of interest today, and at least those in the pharmaceutical industry ought to be interested in as well.

This has been a wonderful hearing. I am very appreciative. You are all top people in your fields, and I have picked up a lot from this hearing. We just hope we can put together legislation that will be beneficial for most everybody.

We appreciate any further help or assistance you can give us. You folks really understand this better than anybody because you are right on the front lines in these areas. It is an extremely interesting area. I do not want to see us foul it up, and we have a tendency to do that up here on Capitol Hill, so we need some help.

You guys should not be giving those big grins when I say we are fouling it up. That was just a nice little admission by me, and I cannot blame you for grinning. I think I fully understand.

I am just grateful that you all took the time to come and visit with us today. This has been a particularly prescient panel, and it means a lot to me. Thank you for being here, and we will recess until further notice.

[Whereupon, at 3:45 p.m., the Subcommittee was adjourned.]

[Submissions for the record follow.]

[Additional material is being retained in the Committee files.]

SUBMISSIONS FOR THE RECORD

AMGEN®

Testimony Before the Senate Judiciary Committee's
Subcommittee on Intellectual Property
July 26, 2005

Mr. Chairman, Senator Leahy and Members of the Subcommittee,

Thank you for the opportunity to testify today.

My name is David Beier and I am Senior Vice President for Global Government Affairs for Amgen, a health care biotechnology company.

Amgen's mission is to serve patients. As the world's leading biotechnology company, we use scientific discovery and innovation to produce medicines that dramatically improve people's lives. For nearly 25 years, the company has harnessed the powerful tools of cellular and molecular biology and medicinal chemistry to discover, develop, and commercialize proteins, antibodies, and small molecules that can extend the reach of medicine. Started as a small business with assistance from the US Small Business Administration (SBA), Amgen was recently inducted into the SBA Hall of Fame.[1] We are one of almost 1,500 biotechnology companies in the United States as of December, 2003.[2]

Originally founded in 1980, Amgen pioneered the development of novel and innovative products based on advances in recombinant DNA and molecular biology. More than a decade ago, Amgen introduced two of the first biologically derived human therapeutics, EPOGEN® (epoetin alfa) and NEUPOGEN® (filgrastim), which became the biotechnology industry's first blockbuster products and provided treatment for hundreds of thousands of patients suffering from conditions of anemia related to chronic kidney disease and neutropenia caused by chemotherapy.

Today, Amgen is a Fortune 500 company whose business has expanded to serve patients around the world in the treatment of anemia, rheumatoid arthritis, supportive cancer care, and other life-threatening and debilitating diseases such as psoriatic arthritis and ankylosing spondylitis[3]. The ability to invent, develop and market these medical breakthroughs was made possible by the promise of strong patent protection and an effective patent enforcement system.

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[1] "Four Exemplary Businesses Inducted into the SBA's Hall of Fame", United States Small Business Administration press release, April 27, 2005 (accessed 7/22/05 at http://www.smallbusinessnotes.com/fedgovernment/sba/sbanews/sbanews042705d.html)

[2] Biotechnology Industry Facts (accessed 7/22/05 at http://www.bio.org/speeches/pubs/er/statistics.asp)

[3] Ankylosing spondylitis (pronounced ank-kih-low-sing spon-dill-eye-tiss), or AS, is a form of arthritis that primarily affects the spine, although other joints can become involved. It causes inflammation of the spinal joints (vertebrae) that can lead to severe, chronic pain and discomfort. In the most advanced cases (but not in all cases), this inflammation can lead to new bone formation on the spine, causing the spine to fuse in a fixed, immobile position, sometimes creating a forward-stooped posture. Spondylitis Association of America website (accessed 7/22/05 at http://www.spondylitis.org/about/as.aspx)

Biotechnology is revolutionizing the war against disease and boosting the American economy – but this revolution depends upon strong and reliable patent protection.

Saving Lives
Biotechnology is saving lives and holds the promise of breakthrough solutions for many devastating diseases and conditions for which there is currently inadequate treatment or no treatment. Enormous investments in biotech have made possible the industry's medical breakthroughs, including

- new cancer drugs that take specific aim at tumor cells,
- "clot-buster" drugs that dissolve clots that cause heart attacks and strokes, dramatically reducing disability and death from these health episodes,
- a drug that can help inhibit the progression of joint damage and dramatically improve the health and well-being of patients suffering from rheumatoid arthritis and juvenile rheumatoid arthritis,
- products that stimulate red and white blood cell production and reduce disability and death from anemia and infection associated with chemotherapy and kidney disease.

Over 325 million people worldwide have been helped by the more than 155 biotechnology drugs and vaccines available today.[4]

Benefiting the Economy.
The biotech medicines industry is also a major economic and job-producing asset for the US at a time when concern about losing jobs to low-wage countries is growing.

- Medical biotechnology companies directly employed more than 400,000 Americans in 2003. Jobs in this sector tend to be skilled positions that pay more than $25,000 per year above the average wage.
- For every job in a biotechnology company, on average, 5.7 additional jobs are created in other businesses that support the industry and the daily needs of their employees and families. This multiplier is substantially above the average for all industries.
- In 2003, the industry was responsible for 2.1 percent of total employment in the nation.
- The medical biotechnology sector is among the most productive of the U.S. economy. It was directly responsible for $63.9 billion in real output in 2003.

Biotechnology innovation contributes significantly to improve the health and welfare of the world. However, strong patent protection and a rational, predictable, and efficient patent system are essential to continued biotechnology innovation.

Biotechnology is Uniquely Sensitive to Changes in Patent Law.
Innovation in biotechnology, more than any other industry, depends upon strong patent protection. Discovering and producing safe and effective biologics is uniquely difficult, uncertain, and expensive. Developing biologic drugs requires extensive technical expertise and financial resources. Overall, the cost of drug development is approximately $800 million to $1.2 billion per successful drug.[5] Biotech products take a very long time –12 to15 years – to move

[4]EuropaBio, "Comments on WHO Priority Medicines Project," September 15, 2004 (accessed 10/25/04 at http://www.europabio.org/positions/WHOPriorityMedicines.pdf)
[5] Boston Consulting Group, "A Revolution in R&D – the impact of genomics," *BCG Focus*, June 2001.

from the laboratory to patients.[6] The vast majority of potential products fail. From pre-clinical discovery to FDA approval, biotech has a 10 to 30% success rate.[7] Manufacturing is very complex and expensive. It takes approximately 5 years and $1 billion to build a factory to produce biotech medicines - this time and money must be invested before the company knows if the product works, whether it will be approved by the FDA, and the size of the market. Only three of ten marketed drugs produce revenues that match or exceed average R&D costs.[8]

Investors take significant financial risk to fund the research and development of these life-saving treatments and they rely on laws protecting patents to recover their investment if the product is approved for market. It is impossible to tell prior to making significant R&D investment which of the thousands of promising ideas will become a successful future treatment or cure. Once such success occurs, that product must then fund R&D to create new drugs and therapies that will reduce human suffering, improve quality of life, and save lives.

Without sufficient incentives to invest in life-saving R&D, we will have:

- Fewer cures and treatments discovered
- Fewer promising discoveries making it to market
- Slower access to cures and treatments by patients,
- Less product choice for patients
- Fewer jobs in the biotech and other sectors and therefore a less vibrant economy

Patent Reform Must Support Innovation

Innovation is good for society; it is the single biggest factor determining the rate at which a society improves its ability to deliver longer, healthier, more comfortable lives to its citizens. An effective patent system encourages innovation by providing economic incentives to innovate. To be effective in this regard, the patent system must have the public's confidence. A strong patent system that is transparent, reliable, predictable and enforced will foster public confidence and therefore investment. Biotech, more so than other high tech sectors, needs access to huge levels of venture capital. Those investors need some degree of certainty, and a vital ingredient is a predictable set of rules for obtaining patents, a measure of efficiency and certainty concerning enforcement, and the application of sound science both in the PTO and the courts.

Amgen urges the committee to carefully consider the impact each proposed patent reform change would have on innovation before altering what is widely considered to be the most effective patent system in the world. Congress's first commitment must be to do no harm to industries that are effectively served by the current patent laws. Where the system is not broken, it should not be changed. We recognize that the software and financial services industries have identified legitimate problems with the way the system impacts business activities in those sectors. To those ends, we appreciate the tireless efforts made by Chairman Smith and his staff in the House to proceed cautiously and attempt to secure consensus before embracing wholesale change.

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[6] Biotechnology Industry Organization, "Biotechnology Industry Facts" (accessed 10/25/04 at http://www.bio.org/speeches/pubs/er/statistics.asp); Joseph A. DiMasi, "The Price of Innovation: New Estimates of Drug Development Costs," Journal of Health Economics, Volume 22, Issue 2, March 2003, Pages 151-185 (accessed 10/25/04 at http://www.cptech.org/ip/health/econ/dimasi2003.pdf)

[7] Milken Institute, "Biotechnology Valuations for the 21st Century," April 2002 (accessed 10/25/04 at http://www.dist.maricopa.edu/bwd/biotechpb.pdf)

[8] Pharmaceutical Research and Manufacturers of America, "Why Do Prescription Drugs Cost So Much and Other Questions About Your Medicines" (accessed 10/25/04 at http://www.phrma.org/publications/publications/brochure/questions/questions.pdf)

Patent Reform that Will Deter Innovation

Two aspects of patent reform embodied in a bill introduced in the House (HR 2795) – (e.g. the sections regarding injunctions and post grant opposition) – will undermine the value of patents and therefore hinder innovation in biotechnology and other resource-intensive industries. Perhaps most fundamental to patent rights, and therefore of grave concern to the biotechnology industry, is the proposal to limit a patent owner's ability to enforce a patent through an injunction. Equally troubling is the proposal to establish an additional administrative procedure through which patents can be challenged throughout the life of a patent. Amgen opposes these proposed reforms and urges the Congress to consult with innovative companies in a wide range of industries when considering these changes.

Obtaining Injunctions

The right to enforce a patent against infringement is fundamental to the value of patents. The critical remedy for patent infringement is the issuance of an injunction to prevent future infringing actions. The biotechnology industry and other resource intensive industries rely on the right to exclude others from using the patented information to recover the millions of dollars invested in research and development. However, other industries, lead by the software industry, argue that they are threatened with injunction as a means of unjustly harassing them or extorting fees from them. A number of proposals have been put forth to address this concern through changes to injunction practice – all of which would undermine the exclusivity of patent rights as guaranteed by the Constitution and should therefore be opposed by Congress.

HR 2795 would alter the standards governing permanent injunctive relief where the patent has been found to be both valid and infringed by allowing infringers to continue infringing during the pendency of an appeal. An appeal could take more than four years. Any change in injunction practice would disrupt the well-settled law governing the rights of patent owners to promptly enforce a patent and would lead to greater uncertainty and confusion in the law. Investment in high-cost ventures such as biotechnology will be unacceptably risky if patent owners cannot reliably enforce a patent in a timely manner. If enacted, this legislation would undermine one of the essential functions of a patent – the capacity to prevent the unauthorized use of the patented invention. As C. Boyden Gray, former White House Counsel from 1989 to 1993, noted in his recent article on injunction practice,

> *It is ironic that at a time when intellectual property is assuming a critical role in generating growth and value-added jobs for the U.S. economy and the world, Congress is considering patent law changes that would, if adopted, ultimately destroy one of the crown jewels of our economy. The problem that the proposed legislation seeks to address is real, but not nearly so serious as to justify undermining the patent system, which is one of the very few building blocks of the market economy that are specifically set out in the U.S. Constitution.* "Patent Reform Bill: A Troubling Proposal for the U.S. Patent Law System," BNA's Patent, Trademark, and Copyright Journal Volume 70 Number 1723 Friday, June 3, 2005 page 122.

Although we appreciate the challenge faced by the software industry, it is counterproductive to hinder the ability of legitimate patent holders to enforce their patent rights. For that reason, we urge Congress to decline the proposed changes to injunction practices and work with the many interested parties to find solutions in other areas around which consensus can be built.

Post Grant Opposition

Proposals to establish a "post-grant opposition" procedure available throughout the life of a patent would decrease the efficiency of the patent system, increase the cost of patent prosecution and validity challenges, and add uncertainty to the patent system that will deter investment in innovation. Post grant opposition is proposed as an additional administrative procedure for reviewing patent validity without court involvement. Under the House proposal, the validity of a patent could be challenged in the U.S. Patent and Trademark Office (USPTO) through post grant opposition within nine months after the patent was issued, within six months after a party received a notice of alleged infringement, or any time at the consent of the patent holder. Other proposals allow for an even wider window of opportunity to challenge a patent using post grant opposition.

While we acknowledge and are sympathetic with the concerns of the NAS, FTC, commentators, and some trade groups about patent quality, we are skeptical that implementation of post grant opposition to challenge a patent can achieve the objectives of increasing quality and efficiency in the patent system and reducing litigation costs. Experience in Europe and Japan with similar systems counsels that a post grant system is not a panacea. A variety of patent correction mechanisms are already provided by statute to permit anyone to administratively challenge the validity of a patent in the United States after it has been issued. Many U.S. patent owners have extensive experience in post-grant opposition proceedings in Europe and other jurisdictions and have found that such a procedure is less than satisfactory in both defending their own patents and in challenging third party patents.

In addition to ensuring that the procedures are fair and efficient, our concerns on post-grant opposition center on the following:

1) The quasi-judicial nature, limited discovery and relatively short time frames for the USPTO's opposition panel to consider the arguments presented would make it difficult in many oppositions for the panel to understand and discern the truth. Patents in biotechnology are valuable property rights that should not be easily tossed out. Although costly, litigation usually provides a more fulsome review of the facts and more conviction that the right result was achieved.

2) Imposing an opposition proceeding at the beginning of a patent term erects an additional hurdle to patent enforcement and could serve to shorten the effective term of a patent. Although the proposed legislation attempts to address this concern, the practicality is that a patent owner would have to convince a court to proceed with infringement litigation in the face of an opposition to the patent in the USPTO. By the time that appeals from the opposition are resolved, the patent term could be effectively shortened by four or more years. We believe that this could greatly harm biotech patent owners who may only have 5-8 years of effective patent life after FDA approval to market the drug..

3) Establishing an opposition proceeding places an additional burden on the USPTO, which is already facing a 510,000-application backlog, and may have the actual effect of reducing overall patent quality instead of increasing it as intended.

For these reasons, we recommend that Congress proceed cautiously with regard to an initial opportunity to challenge patent validity in a post grant opposition. However, we

strongly oppose adopting a so called "second window" for challenging patents in a post grant opposition system. The "second window" in post grant would be inefficient and would undermine innovation in biotechnology and other resource-intensive sectors. Proposals to create a "second window" in which patent validity can be challenged in the USPTO upon notice of infringement enable a challenger to force a patent holder into the USPTO process, in addition to court, for determinations of patent validity. This would inefficiently split into two separate forums the determination of validity and the determination of infringement. Because these determinations are largely based on the same set of detailed and technical facts, this split would require two different bodies to examine the same facts, significantly increasing the resources both patent holder and alleged infringer must invest as a result of presenting the case twice to two different forums.

The second window also negates the possible merit that post grant opposition enables patent holders, challengers, and investors to learn at the beginning of the patent term the scope and validity of the patent. Challengers would have incentive to wait until threatened with a notice of infringement before bringing an opposition to the USPTO, thus making the first window less effective in enhancing patent quality and certainty. Furthermore, allowing post grant opposition challenges throughout the life of the patent would delay a patent owner's ability to enforce a patent because the infringement suit could be postponed until the opposition is completed. This would significantly increase uncertainty for patent holders and investors, and therefore discourage investment in industries that rely on strong patent protection. Finally, the second window would increase dramatically the number of oppositions likely to be presented to the USPTO for consideration, before it is clear the opposition process is effective or efficient, excessively burdening the USPTO.

Rather than implementing a new post-grant opposition system, it would be preferable to eliminate the current inequities in the *inter partes* reexamination system. In the USPTO's report to Congress there are specific recommendations on how the existing *inter partes* reexamination system can be made more effective.[9] Fixing the current *inter partes* reexamination system would be more efficient than adding another administrative process. Rather than reducing bad faith challenges to good patents, implementing a post grant opposition procedure would create yet another forum in which patent holders can be harassed. This additional burden will weigh heaviest on small patent holders with limited resources.

In the event that Congress chooses to adopt a post grant opposition procedure, it is essential that the threshold for invalidating a patent in court – clear and convincing evidence – be applied in the USPTO proceeding as well. It is impractical to apply two different standards to the same question of patent validity; such an arrangement would almost certainly raise more questions than it answers and result in absurd outcomes. For example, it appears that under the proposal where there is a stay of the opposition pending the outcome of the enforcement litigation in HR 2795 an infringer could lose in court on the clear and convincing standard but later win in the USPTO and invalidate a patent on the preponderance of the evidence standard.

It is appropriate to require a challenger in post grant opposition to demonstrate by a standard of clear and convincing evidence that a patent is invalid. Other administrative procedures within the USPTO that apply the preponderance of the evidence standard are effectively an extension of

[9] United States Patent And Trademark Office Report To Congress on *Inter Partes* Reexamination Report available through the USPTO web-site at: http://www.uspto.gov/web/offices/dcom/olia/reports/reexam_report.htm

the examination process and allow extensive revision of claims. In contrast, a post grant opposition proceeding as proposed in HR 2795 is an adversarial adjudication process and guarantees only a single opportunity to amend a claim. A clear and convincing standard would provide some limitation on the number of oppositions filed, prevent abuse of the opposition process and allow the significant property right of a patent to be invalidated only when the facts clearly so establish.

Patent Reform to Enhance Innovation
The following are changes to the patent system that Amgen believes enhance innovation in all sectors.

1. ***End patent fee diversion***
   Adequate funding for the USPTO must be the foundation for any other patent reform efforts. It is widely recognized that the USPTO lacks sufficient funds to hire, train and retain skilled examiners that can consistently make high-quality determinations as to whether patent applications deserve to be granted. The USPTO has been funded exclusively by user fees for over ten years. A significant portion of the user fees collected by the USPTO is diverted to other government uses. In the past decade, $650 million dollars, approximately ten percent of all the user fees paid to the USPTO, have been diverted. Ending fee diversion is an important step in securing adequate funding for the USPTO.

2. ***Prohibit the pleading of inequitable conduct unless one or more patent claims is declared invalid by court; establish "but for" as the threshold for the court holding a patent invalid.***
   The legal standard for inequitable conduct should be modified to more effectively target egregious behavior and reduce the threat of snaring well-intentioned disclosures in a confusing standard that carries with it the patent equivalent of the death penalty. The law currently allows patents to be granted only for inventions that are novel and not obvious, as determined by a review of "prior art." In the United States, there is a duty to disclose to the USPTO any prior art of which the applicant is aware and that is material to the patentability of the invention.[10] Failure to comply with this obligation – for instance, by disclosing too little information that is "material" – can result in a determination that the applicant engaged in "inequitable conduct", thereby rendering unenforceable any patent that might issue on the application even if the patent is still adjudged to be valid. The allegation of inequitable conduct is raised as a defense in nearly every patent litigation and has become a "cancer" on the practice of patent law. To address this, the Law should be changed to allow inequitable conduct to be plead as a defense only after one or more patent claims has been held invalid by a Court. The standard for inequitable conduct should be a "but-for" test: that is, but for the conduct, the PTO would not have issued the patent.

3. ***Change the willful infringement doctrine to permit punitive damages only for egregious offenses, including theft and deliberate copying.***
   Making, using, selling or offering to sell patented material without the permission of the patent owner is considered patent infringement. If the infringement is

[10] Quoted from Arnold B. Silverman, "Disclosing Prior Art to the U.S. Patent and Trademark Office," JOM 49 (7) (1997), p. 74 (accessed at http://www.tms.org/pubs/journals/JOM/matters/matters-9707.html)

found to be "willful," the court may sanction the offender by awarding up to three times the amount of damages.[11] The doctrine was intended to deter patent infringers, but in most cases all that infringers have to do is to have an opinion of counsel that the patent is either invalid or not infringed to avoid a finding of willfulness. Since this does not deter infringers, the doctrine has seemingly ceased to serve its purpose. The law on willful infringement has forced companies to take one of two approaches: 1) seek opinions of outside attorneys on every third party patent that poses a threat even if you believe that you do not infringe, or 2) avoid reading competitors' patents, even for the purpose of determining what patents the applicant might be infringing, in order to avoid being found "willful."[12] The first approach imposes significant financial burdens on companies while the second approach is contrary to the purpose of the patent system to disseminate information on new technology and thereby foster innovation.[13]

The law on willful infringement should be changed to allow punitive damages only in the most egregious cases such as where there has been deliberate copying or continued infringing activity after a judicial determination of infringement and validity.

4. ***Eliminate the "best mode" requirement.***
Best mode is a subjective requirement of the patent law that requires disclosure of the "best way" known to an inventor of practicing the claimed invention. Whether or not the patent applicant submitted the best mode is widely litigated and requires extensive – and expensive – discovery. Because attacks on best mode are more of a threat to patents than an aid to promote disclosure, the best mode requirement should be eliminated. It is noted that in current patent harmonization discussions serious consideration is being given to non-inclusion of the best mode requirement as the best alternative for the world. For these reasons, the best mode requirement should be eliminated.

5. ***Permit assignee filing of patents.***
The process of filing a patent application can and should be simplified and streamlined by permitting an assignee to file. Currently inventors are required to file with the patent office a declaration of assignment before the assignee – typically the employer of the inventor – may sign a declaration in a patent application. Allowing the assignee to sign the application without the inventor submitting additional paperwork will simplify the filing of patent applications by assignee companies. The assignee would be required to identify the actual inventor and certify that the assignee believes the inventor to be the true and original inventor. Moreover, other countries have adopted this practice and it has worked well.

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[11] 35 U.S.C. § 284; Federal Trade Commission, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, A Report by the Federal Trade Commission," October 2003 at Summary page 16, Chapter 5 page 28-29.
[12] Federal Trade Commission, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, A Report by the Federal Trade Commission," October 2003 at Chapter 5 page 29.
[13] Federal Trade Commission, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, A Report by the Federal Trade Commission," October 2003 Chapter 5 page 29.

6. ***Eliminate the exception to the requirement that all patent applications be published within 18 months of filing***
   Publication of patent applications is an important means of facilitating the dissemination of information and should be applied to all patent applications uniformly. Patent applications submitted around the world are made public 18 months after filing. However, in the United States there is an exception to this publication requirement if a patent applicant certifies that the applicant does not intend to file the application in any other country and has not already filed in another country. This exception defeats one of the important objectives of the patent system, that is, increasing information in the public domain, without providing any significant public benefit. Elimination of this exception will more effectively achieve the objectives of the patent system and help to harmonize patent laws around the world. Further, adoption of 18-month publication of *all* applications will eliminate submarine patents. It also provides inventors the benefit of provisional rights for published application claims that are identical or substantially similar to those contained in the granted patent.

7. ***End restriction practice and implement a "unity of invention" standard instead***
   For decades, the USPTO has used "restriction practice" – that is, the policy of dividing related types of claims into separate patent applications – to increase fees and narrow the scope of examination of an application. Not only does this process increase the cost of securing a patent because of increased application fees, it also results in delays in the issuance of the patents, effectively shortening the effective patent life of a drug. Most of the rest of the patent world uses a "unity of invention" standard to determine whether a single application may contain claims to multiple inventions. In practice, unity of invention allows multiple related inventions having a common inventive contribution in one patent to a much greater extent than restriction practice. The United States should move to a unity of invention standard for all patent applications.

8. ***Adopt the "first inventor to file" standard.***
   In every country except the United States, patents are awarded to the first to file a patent application. In the United States, a patent may be awarded only to the first inventor of a product. Relying on invention date creates a significant level of uncertainty for the patent holder because it is only after litigation and discovery that the patent holder can be certain the references used to determine the invention date are reliable and therefore the patent holder is the first inventor under the law. By contrast, a first to file system allows for a greater level of certainty because the filing date is easily established. The international community has long urged the United States to adopt the international standard for purposes of regulatory harmonization. The concern of small inventors that their patent rights will be lost, for instance by the person who hurries to the patent office after stealing the inventor's work, have been addressed by specifying that it is the first "inventor" to file, not just the first to file, that will be granted the patent. Adopting the new universal standard will increase patent predictability and therefore reduce the risk to those who rely on patent rights.

Conclusion

In summary, to preserve the integrity of the U.S. patent system and maintain the market incentive for R&D, any patent law reform must be aimed at encouraging innovation. Amgen supports patent law reform that supports innovation and enhances the U.S. patent system to address the economic needs of the country for the 21st Century. The USPTO should be adequately funded

and be given access to all the fees it collects with the expectation that quality of examination will improve, valid patents will issue on original examination, and patent pendency will be substantially reduced. Injunctions should be readily obtainable by patent owners when their valid patents have been infringed. The plague of inequitable conduct defenses as they are now being played out in the courts should be eradicated. Enhanced damages should be awarded only where there is reprehensible conduct found. The system should be streamlined and improved by eliminating antiquated relics of the current system such as the best mode requirement, limitations on assignee filing, exceptions to 18 month publication, restriction practice, and interferences to determine who among competing parties was the first inventor. To the extent that it is adopted, post grant opposition should apply the clear and convincing evidence standard used in court to invalidate a patent and include only one nine-month window of opportunity to initiate an opposition immediately after the patent has been granted.

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REMEDIES

Among the proposals incorporated in the patent reform bill being considered in Congress is a measure that would remove the presumption that, upon a finding of infringement, the patent holder will suffer irreparable harm unless an injunction is imposed. The measure is meant to address a real problem resulting from serious faults in the patent system, such as the patenting of business methods that should be deemed as obvious. However, such defects should be addressed directly rather than taking a step that would seriously weaken patentees' exclusive rights.

Patent Reform Bill: A Troubling Proposal for the U.S. Patent Law System

BY C. BOYDEN GRAY

It is ironic that at a time when intellectual property is assuming a critical role in generating growth and value-added jobs for the U.S. economy and the world, Congress is considering patent law changes that would, if adopted, ultimately destroy one of the crown jewels of our economy. The problem that the proposed legislation seeks to address is real, but not nearly so serious as to justify undermining the patent system, which is one of the very few building blocks of the market economy that are specifically set out in the U.S. Constitution.

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Some companies in the software and other industries are advocating changing the law to make it much more difficult for patent holders to get injunctions against patent infringement. Their suggested change is embodied in Section 7 of the House committee print of the Patent Act of 2005.[1] These companies are reacting to infringement lawsuits that arise because the current patent system too often does a poor job of sorting out bad patents from good ones. In software, for example,

[1] The House Judiciary Subcommittee on the Courts, the Internet, and Intellectual Property has been using the committee print as a template for drafting its own patent reform bill. The committee print is available at http://judiciary.house.gov/media/pdfs/comprint042005.pdf (visited May 26, 2005) (69 PTCJ 652, 4/22/05; 69 PTCJ 688, 4/29/05; 70 PTCJ 8, 5/6/05).

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the issuance of a large number of dubious or ambiguous patents has given rise to a large number of infringement lawsuits. The speed of software innovation, the difficulty of researching past inventions, and other factors have contributed to this problem.

But the committee print version of Section 7 would cause much more harm than good. It would have devastating consequences for companies and industries that especially rely on patents to justify the enormous investments of time and resources needed to produce innovation—including the biotechnology, pharmaceutical, and chemical industries. This is because the essence of the protection for ideas is the right to stop others from using or stealing those ideas—and Section 7 would relegate the typical holder of a valid patent to a money damages action as his or her only remedy for infringement. Making damages the main remedy for infringement would mean that patent owners would lose the power to keep infringers' hands off their inventions. Instead, owners would effectively be forced to sell infringers a license to use their patented inventions. This would largely eliminate a right that has been integral to the protection of ideas since the early days of the republic. It would put the United States out of step with most industrialized nations. Worst of all, it would sharply diminish incentives to invent and innovate.

It is unsurprising, then, that an alternative version of Section 7 has also been proposed as a basis for discussion.[2] This alternative Section 7 is not quite so terrible as the committee print version of Section 7. But that is not to say that it is worth adopting. Like the committee print version, alternative Section 7 would undercut the availability of injunctive relief for owners of valid, legitimate patents who seek to protect their property.

Historical Background: Public Policy, Patents, and Injunctions

There is a strong public policy justification for providing inventors with a temporary, exclusive right to the use of their inventions. Exclusive rights encourage investment in invention and innovation. "The encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude."[3] Valuable new discoveries and inventions do not fall from the sky. They often come to us only after someone has poured years of hard work and substantial amounts of capital into creating them. These investments are not likely to occur without reliable incentives. Exclusive rights for inventors provide these incentives: they ensure that the fruits of inventions are reaped by the owners rather than by clever competitors.

The importance of this incentive structure for U.S. economic security and prosperity has grown immeasurably since the Constitution was first adopted. The U.S. economy no longer rests on agriculture or manufacturing. It rests on the development and use of valuable ideas. These activities require huge investments of time and capital. In 2003, for example, biotechnology companies spent $17.9 billion on research and development. These projects take years, often a decade or longer, from start to finish. Many of them do not pan out.[4] The companies that initiate such projects, and the capital markets that finance them, invest in the projects only because the patent system guarantees that others will not profit from their inventions.

Because patent and other intellectual property rights are so crucial to innovation, U.S. law—both constitutional law and statutory law—gives them robust legal protection. In Section 8, clause 8, of Article I of the U.S. Constitution, the founders authorized Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors, the *exclusive* Right to their respective Writings and Discoveries." (Emphasis added.) These rights are exclusive precisely because they are intended to spur innovation. In the Supreme Court's words, "[t]he patent laws 'promote the Progress of Science and useful Arts' by rewarding innovation with a temporary monopoly."[5] In keeping with this constitutional understanding, the federal statutes define a patent as "a grant to the patentee, his heirs or assigns, of the right to exclude others" from making, using, offering for sale, selling, or importing an invention (or the products of an invention that is a process).[6]

The Constitution protects patent rights as property notwithstanding their intangible character. In particular, the Supreme Court has repeatedly held that patent rights are protected as property by the takings clause of the Fifth Amendment.[7] This is unsurprising. As the high court has said, "[t]he hallmark of a protected property interest is the right to exclude others."[8] And for patents, "the right to exclude others is central to the very definition of the property interest."[9] Indeed, "[t]he right to license [a] patent, exclusively or otherwise, or to refuse to license at all, is 'the untrammeled right' of the patentee."[10]

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[2] This alternative version of Section 7 apparently is not yet available on the Internet. My understanding is that it is part of a new template to develop a bill that will be the subject of an upcoming subcommittee hearing.

[3] *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 599, 220 USPQ 343 (Fed. Cir.) (29 PTCJ 503, 3/14/85), *modified on rehearing on other grounds*, 771 F.2d 480, 226 USPQ 985 (Fed. Cir. 1985) (30 PTCJ 461, 9/5/85).

[4] *See Dawson Chemical Co. v. Rohm & Haas Co.*, 448 U.S. 176, 221-22, 206 USPQ 385 (1980) (footnotes omitted) ("The number of chemicals either known to scientists or disclosed by existing research is vast. It grows constantly, as those engaging in 'pure' research publish their discoveries. The number of these chemicals that have known uses of commercial or social value, in contrast, is small. Development of new uses for existing chemicals is thus a major component of practical chemical research. It is extraordinarily expensive. It may take years of unsuccessful testing before a chemical having a desired property is identified, and it may take several years of further testing before a proper and safe method for using that chemical is developed.").

[5] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 730, 62 USPQ2d 1705 (2002) (64 PTCJ 98, 5/31/02) (quoting U.S. Const. art. I, § 8, cl. 8).

[6] 35 U.S.C. § 154(a)(1).

[7] See, e.g., *Festo*, 535 U.S. at 730 (patent "is a property right"); *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1003-04 (1984) (trade secrets protected by state law are "property" under the takings clause); *Hollister v. Benedict & Burnham Manufacturing Co.*, 113 U.S. 59, 67 (1885) (patents).

[8] *College Savings Bank v. Florida Prepaid Postsecondary Education Expense Board*, 527 U.S. 666, 673, 51 USPQ2d 1065 (1999) (58 PTCJ 226, 238, 6/24/99).

[9] *Ruckelshaus*, 467 U.S. at 1011 (trade secrets).

[10] *United States v. Westinghouse Electric Corp.*, 648 F.2d 642, 647 (9th Cir. 1981) (citation omitted). *See also Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1362, 52 USPQ2d 1641

 PTCJ ISSN 0148-7965

Federal courts have the same power to protect patent rights that is used to protect other forms of property. The Patent Act, 35 U.S.C. § 283, provides:

> The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to *prevent* the violation of any right secured by patent, on such terms as the court deems reasonable. (Emphasis added.)

The Federal Circuit has explained why this injunctive power is so crucial to science and innovation.

> Without this injunctive power of the courts, . . . the express purpose of the Constitution and Congress, to promote the progress of the useful arts, would be seriously undermined. The patent owner would lack much of the "leverage," afforded by the right to exclude, to enjoy the full value of his invention in the market place. Without the right to obtain an injunction, the right to exclude granted to the patentee would have only a fraction of the value it was intended to have, and would no longer be as great an incentive to engage in the toils of scientific and technological research.[11]

In the United States, the decided preference for injunctive relief over damages as the only effective way to protect innovation goes back more than 150 years. Justice Joseph Story said 160 years ago that "[a] bill will lie for an injunction, if the patent right is admitted or has been established, upon well grounded proof of an apprehended intention of the defendant to violate the patent right."[12] And the Second Circuit, explaining "well settled and familiar" legal principles, said in 1897 that "[t]he principle upon which all injunctions are granted in patent causes, preliminary and final, is that an action at law [in other words, for damages] does not give a complete remedy to the complainant whose property is invaded."[13] A patent infringement was "a constantly recurring grievance, which cannot be adequately prevented but by an injunction."[14] If only damages were awarded for violation of patents and copyrights, "the inventor or author might be ruined by the necessity of perpetual litigation without ever being able to have a final establishment of his rights."[15]

Current U.S. law reflects this established understanding of the need to protect patents with injunctive relief. Once a court has found that a valid patent will be infringed, the law presumes that the owner will suffer irreparable harm—a key prerequisite to the availability of injunctive relief. Because damages alone typically do not prevent irreparable harm, courts almost always grant permanent injunctions at the end of a case if the plaintiff has proven infringement of a valid patent. The rare exceptions are typically cases that might otherwise result in public health disasters.[16] By contrast, courts are more likely to find that the presumption of irreparable harm has been overridden when they are asked to issue preliminary injunctions to protect patent owners during the pendency of a case.[17]

The presumption of irreparable harm flows from "the public policy underlying the patent laws."[18] As the Supreme Court noted nearly 100 years ago, a patent right "can only retain its attribute of exclusiveness by a prevention of its violation. Anything but prevention takes away the privilege which the law confers upon the patentee."[19] In short, "[t]he heart of [a patent owner's] legal monopoly is the right to invoke the State's power to prevent others from utilizing his discovery without his consent."[20]

An Unsettling Proposal

Section 7 of the House committee print would undermine patent owners' basic right to protect their investments. Section 7 would amend 35 U.S.C. § 283 by turning the current version of Section 283 into subsection 283(a) and adding a new subsection 283(b). Under subsection (b), the courts would be barred from "presum[ing] the existence of irreparable harm." In each case, the courts would have to "consider and weigh evidence that establishes or negates any equitable factor relevant to a determination of the existence of irreparable harm." "Any equitable factor" would "includ[e] the extent to which the patentee makes use of the invention." The presumption of irreparable harm would disappear.

This would be a big shift. Under current law, a patent owner knows that he or she can stop someone else from using his or her property. But under Section 7, the owner could not get an injunction even after the court found that the patent is valid and that the patent is being infringed. The patent owner would have to offer proof of something *other* than ownership of a valid, infringed patent in order to get an injunction protecting his or property. What that something is, Section 7 does not say. But Section 7 is clear that proof of intellectual property theft is not sufficient to get a court order preventing the theft. In practical terms, the new presumption would be a presumption *against* irreparable harm – and, therefore, against injunctive relief. Damages would become the standard remedy for future patent infringements.

There are strong reasons why this drastic change should not be made. First, Section 7 would be grossly

(Fed. Cir. 1999) (59 PTCJ 63, 11/11/99) (citing *Westinghouse* and other cases).

[11] *Smith International Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1577-78, 225 USPQ 889 (Fed. Cir. 1983) (26 PTCJ 535, 10/20/83).

[12] *Woodworth v. Stone*, 30 F. Cas. 593, 594 (C.C.D. Mass. 1845) (No. 18,021).

[13] *Allington & Curtis Manufacturing Co. v. Booth*, 78 F. 878, 879 (2d Cir. 1897).

[14] *Id.*

[15] *Id.*(citation omitted).

[16] See *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1547, 35 USPQ2d 1065 (Fed. Cir. 1995) (en banc) (50 PTCJ 197, 6/22/95) (citing cases where injunctions would have curtailed use of cancer and hepatitis test kits, cure of rickets in children, and operation of Lake Michigan sewage disposal plant).

[17] See, e.g., *Rosemount Inc. v. U.S. International Trade Commission*, 910 F.2d 819, 821-22 (Fed. Cir. 1990).

[18] *Smith International*, 718 F.2d at 1581. Also, the presumption "derives in part from the finite term of the patent grant, for patent expiration is not suspended during litigation, and the passage of time can work irremediable harm." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1247, 9 USPQ2d 1913 (Fed. Cir. 1989) (37 PTCJ 382, 2/23/89).

[19] *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405, 430 (1908).

[20] *Zenith Radio Corp. v. Hazeltine Research Inc.*, 395 U.S. 100, 135, 161 USPQ 577 (1969).

unfair. If it is enacted into law, its effect would not be limited to the attention-getting "patent trolls" who abuse the system by (for instance) leveraging dubious patents for common business processes. Section 7 would apply equally to a biotechnology company that spends many years and tens of millions of dollars to develop a truly innovative product, and that depends on the ability to make exclusive use of its innovations to be able to recoup that investment. By losing their presumptive right to get an injunction, this and many other innocent patent owners would largely lose their exclusive rights in their inventions. This drastic and overbroad curtailment of legitimate innovators' rights is especially unnecessary when, as is discussed below, narrower reforms can target the dubious patents that cause the problems in the first place.

Second, as is noted above, the United States has long recognized that substituting damages for injunctive relief would have devastating effects on innovation. Without the right to an injunction, patent owners would effectively be compelled to license their technology to their competitors. The price of the licenses would not be set by the market. Instead, owner and infringer would litigate the question of the economic value of licenses.[21] Stripped of their fundamental attributes as rights to exclude competitors, patents would lose much of their value.

A system of compulsory licensing for patented inventions would undermine the basic purposes for which the patent laws, and their constitutional foundations, were created. As the Supreme Court has said, "[t]he federal patent system . . . embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years."[22] Remove protection for one side of the bargain, and the other side is likely to suffer as well.

It is true that compulsory licenses are occasionally imposed on patent owners — most often, as a remedy for antitrust violations or as a condition of antitrust approval of a transaction.[23] But these narrowly circumscribed situations are not analogous to the typical case of the law-abiding owner and constitute a rather limited exception of licensing that proves the rule of injunctive relief over damages.

Third, Section 7 would undercut the important goal of harmonizing world patent laws and regulations. The right to use an injunction to protect patent rights, in one form or another, is part of the law of most major industrialized countries. Section 7 would depart significantly from this consensus.

Finally, Section 7 could raise serious questions of constitutionality under the takings clause. A patent is the right to exclude others from using inventions. Take away the right to exclude, and you take away the patent. Many technology innovators have made massive investments in research and development that will not result in patent applications until after the date when Section 7 would take effect. Because these investments were reasonably made in reliance on the promise of an enforceable right to exclude, the government might be required to award hundreds of millions, or perhaps even billions, of dollars to some of these inventors for the reduction in patent values that forced licensing would entail.

Real Problems, Wrong Solution

Section 7 is a bad idea, but it should not be denied that the current patent system suffers from some significant defects. A few examples:

- Some patents are too ambiguous. As the Supreme Court has said, clarity on the scope and limits of patent rights "is essential to promote progress, because it enables efficient investment in innovation. A patent holder should know what he owns, and the public should know what he does not."[24] The boundaries of too many patents are much too uncertain. The only way to know the boundaries is to file a lawsuit—or risk getting sued yourself—and then wait, not just for trial but also through an appeal, to get the answer.
- Some patents are too broad. This gives the patentee rights that extend far beyond anything that he or she contributed, and shuts out inventors in the same field.
- Some patents cover things that shouldn't be patented at all—such as business methods that are obvious to persons of ordinary skill in the business. When patents issue for things that are obvious, this hurts innocent competitors of the patent owners.
- Patent examiners don't have the resources they need to make the most accurate decisions on patent applications, and to separate wheat from chaff. Databases for searching past inventions are inadequate in some subject matters, e.g., computer software. That inadequacy leads to imprudently issued new patents, as well as inadvertent infringements of existing patents.

There is no single fix to bad patents, legal uncertainty, and other problems that beset the current system. But

[21] "[C]ompulsory licensing places the court in the position of price regulator—a task for which it is very poorly suited." 3 Phillip E. Areeda and Herbert Hovenkamp, *Antitrust Law* ¶ 705c (2002). By contrast, an injunction "creates a property right and leads to negotiations between the parties. A private outcome of these negotiations—whether they end in a license at a particular royalty or in the exclusion of an infringer from the market—is much preferable to a judicial guesstimate about what a royalty should be. The actual market beats judicial attempts to mimic the market every time, making injunctions the normal and preferred remedy." *In re Mahurkar Patent Litigation*, 831 F. Supp. 1354, 1397 (N.D. Ill. 1993), aff'd, 71 F.3d 1573 (Fed. Cir. 1995).

[22] *Bonito Boats Inc. v. Thunder Craft Boats Inc.*, 489 U.S. 141, 150-51, 12 USPQ2d 9 (1989) (37 PTCJ 377, 391, 2/23/89). *See also Pfaff v. Wells Electronics Inc.*, 525 U.S. 55, 63, 48 USPQ2d 1641 (1998) (57 PTCJ 24, 11/12/98).

[23] *See United States v. Glaxo Group Ltd.*, 410 U.S. 52, 64, 176 USPQ 289 (1973) (112 PTCJ A-1, E-1, 1/25/73) ("Mandatory selling on specified terms and compulsory patent licensing at reasonable charges are recognized antitrust remedies.") (citing cases); Areeda, *Antitrust Law* at ¶ 705c ("[C]ompulsory licensing may be the only remedy for some antitrust violations involving patents, but even then it must be used sparingly."). See also, e.g., 42 U.S.C. § 7608 (authorizing a federal court to compel licensing to enable compliance with pollution control requirements, but only on certain conditions, and only after action by both EPA and the Justice Department).

[24] *Festo*, 535 U.S. at 730-31.

PTCJ ISSN 0148-7965

some partial solutions are commonly recognized—and are part of current proposals (including the committee print). To name only a few, we need to do whatever it takes to empower the Patent and Trademark Office to do its job of granting patents that are deserved, and refusing to grant those that are not. In recent years, demands on PTO resources have sharply increased.[25] Where possible, the patent laws should be changed to make litigation, and defining the boundaries of patents, less complex and costly. And work should continue on harmonizing the world's three most important patent examination systems, those of the United States, Europe, and Japan. None of these steps requires curtailing the enforcement rights of legitimate innovators who depend on those rights when they decide whether to undertake research programs lasting tens of years and costing hundreds of millions of dollars.

Some advocates of Section 7 express concern that injunctions permit a patent holder to stop the manufacture of an entire product simply because a minor component of that product may infringe the holder's patent. But unless the patent on the component is itself illegitimate, the owner of a valid patent commits no injustice by enforcing his or her rights to prevent infringement. To the extent the infringing component is truly minor, it may be possible to redesign the product to avoid the infringement. But it is appropriate to put that burden on the infringer rather than on the party holding a legitimate patent. In any event, this is something that is best handled in individual cases rather than by crippling the injunction remedy generally; for under current law, courts have and habitually use the equitable power to craft their injunctions narrowly to prohibit only the specific activities that constitute infringement.

Some people may be generally worried that patent owners are using their rights to gain unfair advantages over competitors. The shortest response to that concern is that patent owners do not get a free pass to break the antitrust laws. Those laws apply to the anti-competitive abuse of all kinds of property rights, including rights in patents.[26]

A Not Very Useful Alternative

The alternative version of Section 7 is not quite so bad as the committee print version. But this alternative Section 7 has its own problems. At best it is superfluous. At worst, it could have the same effect as the committee print's Section 7.

The alternative version of Section 7 would add two sentences to 35 U.S.C. § 283. As amended, Section 283 would read as follows:

> The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable. *Unless the injunction is entered pursuant to a non-appealable judgment of infringement, a court shall stay the injunction pending an appeal upon an affirmative showing that the stay would not result in irreparable harm to the owner of the patent and that the balance of hardships from the stay does not favor the owner of the patent. In determining equity the court shall consider the fairness of the remedy in light of all the facts and the relevant interest* [sic] *of the parties associated with the invention.* (Emphasis added.)

Everything but the first sentence would be new.

The first sentence of alternative Section 7 ("Unless the injunction is entered . . .") does not seem to be addressed to any problem that actually exists under current law. The district courts regularly stay injunctions pending appeal in accordance with the Federal Circuit's flexible approach to motions for stay of injunctions. In addition, the Federal Circuit can and does temporarily stay injunctions while appeals to it are pending.[27] To the extent that the first sentence would work a substantive change in the standard for granting stays, it would knock out the careful balancing of interests that the courts are performing under current law.

The second sentence ("In determining equity . . ."), on the other hand, can be read as trying to achieve the same goal as would the committee print version of Section 7. That goal is to make it much harder for a patent owner to obtain an injunction against patent infringement. The phrase "[i]n determining equity" is ambiguous, and it may refer to the "principles of equity" by which a court determines whether an injunction should issue in the first place.

Although its effect is likely to be less sweeping than that of the committee print version, the second sentence of alternative Section 7 would significantly undermine the presumption of irreparable harm and the public policy values that this presumption protects. This is for at least two reasons.

First, the second sentence of alternative Section 7 would likely give a court the power to ignore the presumption of irreparable harm whenever it decides that to do this would be "fair."

Second, the second sentence seems to imply that current law does not adequately allow courts to weigh "the relevant interest[s] of the parties associated with the invention." But current law *has* weighed these

[25] The annual number of U.S. patent application filings doubled between 1992 and 2004. The PTO now takes over two years on average to issue a patent. For some subject matters, average pendency exceeds three years. According to the director of the PTO, the three-year delay could double in length by 2008.

[26] *See In re Independent Service Organizations Antitrust Litigation*, 203 F.3d 1322, 1325, 53 USPQ2d 1852 (Fed. Cir. 2000) (59 PTCJ 598, 2/25/00); *Roberts v. Sears, Roebuck & Co.*, 723 F.2d 1324, 1329 n.5 (7th Cir. 1983) (en banc); *Westinghouse* at 647.

[27] See, e.g., *Standard Havens Products Inc. v. Gencor Industries Inc.*, 897 F.2d 511, 512-13, 516, 21 USPQ2d 1321 (Fed. Cir. 1990) (describing flexible approach; granting stay); *Eolas Technologies Inc. v. Microsoft Corp.*, 399 F.3d 1325, 1332, 73 USPQ2d 1782 (Fed. Cir. 2005) (69 PTCJ 471, 3/11/05) (noting that permanent injunction was stayed pending appeal); *NTP Inc. v. Research In Motion Ltd.*, 392 F.3d 1336, 1339, 73 USPQ2d 1231 (Fed. Cir. 2004) (69 PTCJ 159, 12/17/04); *Nautilus Group Inc. v. ICON Health and Fitness Inc.*, 372 F.3d 1330, 1332, 1333-34, and 1334 n.5, 71 USPQ2d 1173 (Fed. Cir. 2004) (68 PTCJ 244, 7/2/04); *International Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363, 1369, 72 USPQ2d 1571 (Fed. Cir. 2004) (68 PTCJ 590, 9/24/04) ("this court granted an emergency motion to stay the [permanent] injunction pending appeal"). Cf. *Collins v. Platts*, 112 Fed. Appx. 25, 25-26 (Fed. Cir. 2004) (vacating permanent injunction); *Honeywell International Inc. v. ABB Inc.*, 71 Fed. Appx. 50, 51-52 (Fed. Cir. 2003) (vacating preliminary injunction).

interests—by establishing the presumption of irreparable harm. Any weighing that departs from the weighing embodied in current law would also depart from that presumption.

Finally, the second sentence of alternative Section 7 would very likely insert a big quantum of unpredictability and arbitrariness into court decisions on whether to protect patents with injunctive relief. Just as it offers no standards for weighing the interests of "parties associated with the invention," the second sentence offers no guidance on determining fairness. This would create a large risk of disparate outcomes in similar cases, as different district judges would rely on whatever standards of fairness appealed to their sensibilities.

Conclusion

It bears repeating that intellectual property rights have been central to the American economy's extraordinary long-term success. This is not the result of accident. It is because American law has afforded intellectual property rights the robust protection that they deserve and need. Weaken the protection, and intellectual property will become something less than property. And the incentives to create and develop it will weaken as well.

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Statement of

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and

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before the

Subcommittee on Intellectual Property
Committee on the Judiciary
United States Senate

Tuesday, July 26, 2005

Mr. Chairman, Senator Leahy and members of the Intellectual Property Subcommittee,

My name is Todd Dickinson and I am honored to appear before the Subcommittee on an issue that may not always ignite the broad passion of some other issues, but one which is critical to our Nation's economic growth and prosperity: patent reform. I presently serve as the Corporate Vice President for Intellectual Property of the General Electric Company, and was formerly Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and I hope that these two distinct though complementary experiences may offer a valuable perspective on some of the issues facing us in this area.

As Director, I enjoyed working with you in the past, Mr. Chairman, and with Senator Leahy and your staffs, on the cause of adapting our patent system to the needs of the 21st Century. I was particularly proud that the Congress passed and President Clinton signed the American Inventor's Protection Act of 1999, during the time I lead the USPTO, and that we had the opportunity to work together on the implementation of that Act, leading to many vital and important changes in how the USPTO operated and was organized.

At General Electric, I am fortunate to help manage the intellectual property assets of one of the world's largest corporations, whose IP holdings and concerns are extraordinarily broad, ranging from content-based copyright issues in our film and television organization, NBC Universal, to genomics and proteomics patenting in GE Healthcare, with everything else in between

from aircraft engines to engineered polymers. It is said that we may be the only company that has won both a Nobel Prize and an Academy Award®. We are also often cited as one of the world's most famous and valuable brands.

In many ways because of that breadth of IP issues and concerns, we are uniquely positioned to participate in this debate about patent reform, being a member of PhRMA, BIO, the Financial Services Roundtable, MPAA, and NAM. I also serve on the Board of Directors of the Intellectual Property Owners (IPO), and the Council of the American Bar Association Section on Intellectual Property Law and as its delegate to the World Intellectual Property Organization's Standing Committee on Patents, and am a member of the American Intellectual Property Law Association.

With such an extraordinary investment in technology, the need to protect that investment and the shareholder value it represents, makes the U.S patent system and its global analogues, more important than ever to us at GE. While our system is one of the greatest and most productive in the world, as with all systems, evolving needs require a regular review and reform in order to ensure the promise of the system is one which is fulfilled. So it is with our patent system in the U.S.

In my previous role as USPTO Director and now at GE, I have also followed with keen interest the various studies of the U.S. patent system recently undertaken by the Federal Trade Commission and the National Research Council of the National Academy of Sciences and the resulting reports. I was a witness several times before both bodies and was a reviewer of the

NAS report. In general, both reports were thorough, well-thought out, and made recommendations the majority of which were highly appropriate to advancing the cause of patent reform in positive ways. I am heartened that the reports have served as a motivation for the cause of patent reform, and applaud this Committee for its hearings on this topic.

Before delving into the patent reform issues, however, I want to briefly address another issue that affects the successful functioning of our patent system. As both the NAS and FTC reports highlighted, the USPTO must have sufficient resources to perform its critical role in administering the patent system. For years, the USPTO was denied these resources as patent and trademark fees, paid to the USPTO in return for specific services, were diverted to unrelated government agencies and activities. While Congress and the current Administration are to be commended for fully funding the USPTO during the current fiscal year, fee diversion from prior years has left the USPTO with a tremendous work backlog, obsolete systems, and an inability to restructure. As contemplated in H.R. 2791, recently introduced in the House, the USPTO should be given authority to raise its fees, and also be given statutory assurance that those fees will not be diverted to unrelated programs. In the event that additional resources are provided, one area where attention should be focused is using those funds to provide additional examination time for examiners.

Harmonization

Turning to patent reform matters, as someone who has also spent a significant amount of time and effort on the cause of international

harmonization of patent systems and laws, I also greatly appreciate the Committee's review of these issues, particularly as they intersect with the work and recommendations of the FTC and the NAS. The U.S. has always taken a leadership role in intellectual property policy and administration in the world, and this debate is in large part about how we can continue to manage and expand that global leadership role.

One of the most critical issues facing the patent system today, globally, is the tremendous need for harmonization of patent laws and systems. With their territorially-based administration, maintenance, and enforcement regimes, the current systems foster extraordinary redundancies in cost, time, and resources. These systems significantly inhibit the ability of inventors, large and small, to obtain and maintain the protection they deserve, and encourage the innovation so vital to global economic development. GE's innovation has resulted in an active global portfolio that comprises over 38,000 patents and this number includes over 5,300 global patent applications in 2004. The cost to obtain and maintain this portfolio is not trivial. In 2004, GE spent in excess of $26,000,000 on the patent prosecution and maintenance of the foreign portfolio, a significant portion of which is a function of the multiplicity of world systems.

Efforts at increased harmonization have been debated for years, with only modest success. As a negotiator of intellectual property issues on behalf of the U.S. government, and as a delegate to the World Intellectual Property Organization, I have witnessed the frustrations in this area first hand. While we have succeeded in negotiating new treaties in many other areas of intellectual property over the last decade to deal with rapidly evolving

changes in the technology and content worlds, patent harmonization has proven particularly difficult and challenging for a variety of reasons. Thus, I welcome the current deliberation on patent reform in the U.S. as an opportunity for informing and influencing this global debate.

First-Inventor-to-File

One of the major obstacles to global harmonization has traditionally been resolution of the basic question of who is entitled to priority of invention. Alone among the world's countries, the U.S. has maintained a system awarding priority of inventorship to the so-called "first inventor". This seemingly innocent characterization has become fraught with difficulties of definition, proof and cost. All of the rest of the world awards priority to the first inventor to file their patent application. While this debate has been ongoing for decades, the time appears to be at hand for the U.S. to join the rest of the world in implementing this simpler, fairer and less burdensome means for awarding priority.

As the groundbreaking study by my colleague and friend, former PTO Commissioner Gerry Mossinghoff, has shown, the very individuals who in recent tradition have been most concerned about this change, the individual or small inventors, have actually been disadvantaged by our current system.[1] The primary means for determining inventorship when there is a contest is a

[1] Interestingly, it should also be noted that, in testimony before this Subcommittee's predecessor, a representative of small inventors once stated, "[W]e endorse a first-to-file rule." Statement of Burke E. Wilford, National Director, the American Society of Inventors, Exhibit D, Hearings before the Subcommittee on Patents, Copyrights and Trademarks of the Committee on the Judiciary, United States Senate, 90th Congress, May 17-18, 1967, p.291.

process in the USPTO known as interference. Costly[2], rule-bound, and time-consuming, the interference process is a failed promise for small inventors.

Moreover, since this was last seriously debated at the international level, during the first Bush Administration, many other structural and systemic changes have helped level the playing field relative to concerns previously expressed. The adoption of provisional applications, the availability of technical and legal resources on the internet, and electronic searching and filing capabilities on-line have made the application process more accessible and timely to all Americans.

This past year, both the NAS report and the American Bar Association's House of Delegates urged the U.S. to change to a "first-inventor-to-file" (FITF) system as a best practice.[3] While it has sometimes been suggested that the U.S. should not unilaterally move to this FITF system, and should only consider it as part of an overall package of international harmonization treaty obligations, the advantages of this system in terms of simplicity, cost, and a serious reduction in uncertainty about priority, argue strongly in favor of making such a change now. It may also be that such a good faith move on the part of the U.S. will reinvigorate stalled negotiations at the WIPO, an important and valuable goal. I join with my colleagues in support of proposed changes that would amend Title 35 to award priority to the first

[2] It is often estimated that the cost of an interference from declaration to resolution is routinely in the hundreds of thousands of dollars.

[3] The applicant must still be the true inventor. .Inventions derived or stolen by others would not permit that deriver or thief to be considered the true inventor. For this reason, the term of art used to describe the new system is "first-inventor-to-file".

inventor to file a patent application, and urge this subcommittee to include language to that effect in any patent reform statute under consideration.

Grace Period

Another extremely valuable and important aspect of U.S. patent law, which has often been linked to the "first-inventor-to-file" issue in international discussions, is the so-called grace period, under which U.S. law provides for a period following disclosure of the invention during which the patent application may be filed. This contrasts with other countries, in particular in Europe, which have a so-called "absolute novelty" system, under which public disclosures of the invention irretrievably bar filing the patent application. The grace period has provided significant and advantageous flexibility, especially for small inventors, and it is critical that it be maintained as part of any patent reform package.

Legislation proposed in the House, H.R. 2795, acknowledges that importance, while making several changes which would seem acceptable and advance the cause of global harmonization. Limiting the applicability of the grace period to the inventor's own disclosures, while indeed limiting, seems a modest change, especially in view of the philosophical underpinnings of the grace period itself. Much of the concern about possible grace period changes has spoken to the loss of rights due to inadvertent or academic disclosures, most of which are made by the inventors themselves.

Another intriguing provision of that bill seeks to strongly encourage the European Patent Convention and the Japanese Patent Convention to adopt a similar grace period in order to allow their respective nationals to take advantage of the grace period in the U.S.[4] While there may be concern about possible backlash from the affected countries, the provision would seem to provide powerful encouragement to them to adopt the compromise they have long-promised in international discussions: "We will adopt the grace period, if you move to first-to-file". Such encouragement may be necessary in order to advance harmonization.

Other harmonization issues

Finally, as to harmonization, there are several additional ideas deserving of serious consideration. These include: elimination of the best mode requirement, permitting the filing of the application by or in the name of the assignee, and publication of all pending patent applications (i.e. eliminating the "opt out" provision in current law). These have been thoroughly considered in either or both of the FTC and NAS studies and have been widely discussed in the IP community. They are worthy and for the most part non-controversial and should be included in any final patent reform legislation.

Post-Grant Review

Of all of the recommendations of the FTC and NAS reports, that which has been the subject of the most discussion and is, in many ways, the

[4] H.R. 2795, § 11(h)

cornerstone of patent reform efforts is implementation of a robust post-grant review or opposition system. This is a direct response to both a strong concern about patent quality and the need for new means to address that concern. Additionally, opposition proceedings are fairly common in foreign patent regimes, the EPO being a significant example, and the adoption of a similar system in the U.S. would also be consistent with the goal of increased global harmonization.

In my experience, the USPTO does a very effective job. I have strong confidence in the strength and validity of the vast majority of issued patents. That said, given the critical importance of patents to our economic health and the need for greater confidence in our system and the ability of the USPTO to maintain and improve patent quality, additional means for improving patent quality are appropriate and necessary. Despite our best intentions, previously implemented mechanisms to address these concerns, such as *ex parte* and *inter partes* reexamination, Rule 99 pre-grant submissions of prior art, and Section 301/Rule 501 post-grant submissions of art, have not, for a variety of reasons, sufficiently met this challenge. There is a critical need for a system which allows the USPTO to continue to improve the quality of issued patents in a timely and efficient manner. For matters of validity determination, the USPTO is uniquely positioned to perform this function, both by virtue of technical expertise and administrative efficiency, if they have adequate access to the appropriate art necessary for the validity determination. A vigorous post-grant review process would allow the USPTO to meet this challenge.

Such a system would likely involve many "moving parts", all of which would need to work together and meet the goals of efficiency and effectiveness. Here again, I would commend H.R. 2795 to you as striking the right balance on most of these issues -- no small feat. For example, the opportunity for adequate discovery in order to address concerns about the estoppel effect of any determination is a key issue. However, this needs to be balanced against concerns about discovery abuse and cost which continue to plague patent litigation. Another concern is the threshold requirement for bringing the action in the first instance. Adoption of a standard similar to that for *ex parte* reexamination, "a substantial question of patentability exists for at least one claim", leaves it to the Director's judgment as to whether that standard has been met, and would require an appropriate showing without unduly burdening the system.

It is heartening to note that there has been widespread agreement and consensus on the need for such a post-grant review system and the appropriateness of the current proposals. There is one specific issue on which there is unfortunately not consensus and no small amount of controversy: the so-called "second window."

"Second Window"

The debate on this issue has centered basically on whether, in addition to the opportunity to request an opposition within 9 months of the issuance of the patent in question, there should be another opportunity to request an opposition; for instance, after receiving notice from the patent holder alleging infringement. Some believe such a "second window" will

unnecessarily increase uncertainty in the validity of issued patents, while others believe a second window allows expanded opportunities for improving quality, especially in industries or technologies where searching or interpretation of claims may be more difficult. While I have concerns about increasing uncertainties, I do believe that the USPTO is a particularly appropriate venue for making validity determinations in a cost-effective and technically sophisticated environment.

That said, one specific concern I would have at the outset is whether the initial administrative burdens imposed by the "second window" may overburden the USPTO during the establishment of what is a new and complex procedure. It may be appropriate to delay the imposition of any "second window" until such time as the opposition system for newly issued patents has been up and running for some period of time, and the USPTO and the public has had adequate time to work with it. This would also provide an opportunity for continued discussion and perhaps the development of greater consensus around the specifics of the "second window" process.

An alternative to consider might be to have the presumption of validity, which a patent current currently enjoys in litigation from the date of issuance, not come into force until the period of opposition has passed. This would encourage review of patents as they issue. It also has a parallel in the trademark system, in which trademark registrations become "incontestable" after a certain period upon the filing of petition and the payment of a fee.

Another alternative to a second window would be to create far more robust reexamination processes. The current limited usage is a function of various concerns, some of which have been addressed in proposed legislation, and others which might create even greater incentives, such as a more routine use of litigation stays in favor of reexamination. One advantage to reexamination in this context is that it can be sought at any point during the term of a patent. If reexamination became a more robust mechanism for challenging validity, it may serve largely the same purpose as allowing a second window for oppositions.

Adequate funding

Finally, regarding the opposition system generally, such a system must be sufficiently funded, from the outset, in order to work well and provide its promised benefits – no small challenge, given recent appropriations concerns. It is highly unlikely that charging opposition fees alone would be adequate, especially without overly discouraging the use of the system. Such funding would almost assuredly have to come from an increase in the USPTO budget, and most likely from a supplemental appropriation in the short-term. I would urge the Congress not to try and fly this plane on one wing – funding is an issue that must be addressed from the beginning.

Pre-issuance Submissions of Art

As noted above, Rule 99 (37 CFR 1.99) permits the submission of art to the USPTO, which is ordinarily subsequent to the publication of an application. While this rule provides the opportunity to have additional art before the

Examiner during examination, 35 U.S.C. § 122 prohibits submitters from rendering such submissions into de facto protests or pre-grant oppositions. Thus, in practice, Rule 99 has not often been used and its benefits have gone largely unrealized -- facts which greatly dishearten me as a strong proponent of the original rule. Criticisms of the USPTO around quality were and are a major concern of mine; getting the best art before the examiner in a timely manner, without unduly slowing the examination process, is one of the most valuable means to address those quality concerns. Moreover, the concerns on which §122 were originally premised seem not to have come to fruition. For these reasons, I support amending §122 to significantly expand the opportunity for such submissions, while protecting the system from inappropriate gaming.

Litigation Reform

Both the FTC and NAS reports recommend reduction in subjectivity in the procurement and enforcement of patents. H.R. 2975 includes several provisions addressing those recommendations. One involves modifications to the law of willful infringement, which may result in the imposition of increased damages. Another modifies the law on inequitable conduct, which currently provides that a patent may be found unforceable due to such inequitable conduct - in particular, when the duty of candor and good faith to the USPTO during prosecution has been breached. There is value in addressing these issues. Despite their good intentions and effect, both have sometimes resulted in negative, unintended consequences, such as a failure to search the patent literature before introducing products into the marketplace, and an generally observed tendency to assert the inequitable

conduct defense in almost all patent litigation, thereby driving up its costs and complexity.

However, H.R. 2975's current treatment of inequitable conduct needs further adjustment. The legislation appropriately retains the duty of candor and enhances the statutory authority of the Director of the USPTO to issue regulations governing the applicants' duty of candor. However, the bill also provides that courts refer all matters of inequitable conduct to the USPTO, and that the agency is then charged with investigating these issues as a matter of attorney or agent conduct, with the ability to conduct hearings and levy not insubstantial fines. As a former USPTO Director, this seems to me to be a difficult and cumbersome mechanism for dealing with this issue. While concerns have been expressed in the past that the current regime, which may render the patent as a whole completely unenforceable, is too drastic, this proposal strikes me as even more drastic, and therefore by extension even less likely to lead to compliance with the duty of candor. In short, it seems to expect the Office to serve as a "disciplinary policeman". The Office's experiences in the past in this regard have not been positive, and it seems reasonable to expect that they would be subject to the same fate under this proposal. I would urge additional review of this particular area.

Injunctions

One issue that has been the subject of possibly the most debate and controversy to this point, but which interestingly was not recommended in either of the major reports from the FTC and the NAS, is changing the standards for injunctive relief. These standards have been the particular

concern of some in the software and financial services industries. The apparent goal is to limit the availability of permanent injunctions in certain circumstances, and thereby purportedly reduce the ability of certain types of patent holders to leverage those patents in litigation or licensing negotiations. These patent holders have come to be identified by the sobriquet "patent trolls."

The possibility of legislation in this area raises several very serious concerns. There is appropriate apprehension about the impact of patent holders whose sole purpose appears to be acquiring and using patents of dubious quality or breadth as speculative investments, without meaningfully adding to technological or economic development. On the other hand, many patent holders are individuals or universities whose only means of competing with much larger entities is using their innovation and the resulting patent protection to negotiate for the development of that innovation.

The challenge arises not so much in identifying the problem, however, (although in my experience I would suggest it is far more limited than its opponents have suggested and may even be aggravated by certain practices on their parts), but rather with the proposed solution. As a property right, and an exclusory one at that, the patent right requires in its very being that it be actively enforceable by the courts against trespass by others. This is particularly true in the case of permanent injunctions that result from final adjudications and appeal. To do otherwise, is to erode the value of the patent portfolio, and for companies like GE, erode shareholder value. We have an enormous investment in research and development, and must have

the ability to protect that investment. To limit our ability to obtain permanent injunctions, is to limit that protection in ways we currently find unacceptable.

Moreover, in the context of international harmonization, such an amendment would send a highly negative signal about the U.S. commitment to enforcing intellectual property rights to those countries or entities in the world who question or oppose such rights. Some nations seeking to impose compulsory license regimes would undoubtedly cite such a law as justification for their actions. As we continue to struggle for both harmonization and the protection of U.S. intellectual property abroad, it would more than counter-productive to send such a signal.

It is for these reasons and others that the various proposals to alter injunctive standards have proven so controversial, and are opposed by most major IP institutions, such as the IPO and AIPLA, as well as independent inventors and universities.

Conclusion

In conclusion, I commend this Committee for diving into the often arcane and esoteric debate on patent reform. This Committee has a real and rare opportunity to craft patent legislation that both has broad support and meaningfully improves our patent system. While virtually any patent legislation, no matter how modest, will generate some level of opposition, the outlines of a passable, yet meaningful bill have begun to emerge.

The opportunity for advancing international harmonization efforts through domestic legislation is a major benefit of proposed legislation. With the prospects for success so clear, it would be doubly disappointing if insistence on inclusion of an injunctive standards provision were to scuttle chances for meaningful patent reform. Surely some other means for attacking the patent troll speculator problem can be found. Other provisions addressing litigation reform have met with general acceptance, and could find their way into law.

I would like to thank the Subcommittee for giving me the opportunity to testify today, and look forward to working with you and your staff as you craft this vital and important legislation.

Statement of Senator Patrick Leahy,
Ranking Member, Judiciary Subcommittee on Intellectual Property
"Perspective on Patents: Harmonization and Other Matters"
July 26, 2005

Today we are holding the third in a series of hearings examining the challenges facing our nation's patent system, and I want to thank Senator Hatch for his continued focus on these important issues. We began in April with a broad overview of the concerns. Then in June, we examined patent litigation in particular and what some see as an overuse and abuse of injunctions in patent litigation.

At those earlier hearings, we learned a great deal about the internal strains on our patent system. The Patent and Trademark Office's workload has increased dramatically during the last few decades. The office issues about 100 patents every working hour, and still there is a backlog of applications to be examined. We also heard complaints that skyrocketing legal costs associated with inventing have created a system in which litigation strategies – rather than innovation strategies – have become more and more important.

Today, we will consider international harmonization of our patent laws. We have heard a number of suggestions on this subject. The one which has attracted the most attention is the question of whether we should switch the U.S. from a first-to-invent standard of patentability to a first-to-file standard. Only U.S. patent law observes a first-to-invent rule, which grants patent protection to the first person to develop an invention, rather than to the first to file a patent application. A first-to-file rule would make our standards consistent with other countries. It might also reduce patent litigation as proving that a person was the first-to-invent can be a difficult, costly, and time-consuming task. But we have also heard that a first-to-file standard could harm small inventors and universities. Like so many topics in our discussions, not everyone agrees, and the issue should be studied carefully before any action is taken.

We can all agree that international harmonization raises interesting questions with serious ramifications, and I look forward to what our witnesses have to say. Greater uniformity in some of our patent processes may provide a more stable and predictable environment for inventors, but we need to ensure that any changes we make – or decide not to make – are the right ones. After all, the United States' place as world leader in intellectual property is owed in no small measure to our own laws. We should be careful to ensure that any changes we make help us retain our competitive edge.

Another issue deals with the publication of patent applications. Most countries publish inventions 18 months after filing a patent application. In the United States, however, an inventor can prevent publication by agreeing not to patent the invention outside of the country. Some say that this is unfair – it can create a situation where a person invests resources in developing an invention that later turns out to be un-patentable.

I look forward to working with the Chairman to see if we can sort out some of these issues. I am also closely watching developments in the House patent reform bill, which I understand has been undergoing some major changes recently. In the end, American inventors have been successful because of our ideas. I hope as the Subcommittee examines the many issues associated with our patent system, we will be no less innovative in our solutions – and no less successful.

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Statement of

Hon. General J. Mossinghoff
Senior Counsel
Oblon, Spivak, McClelland, Maier & Neustadt, P.C.

before the

Subcommittee on Intellectual Property
Committee on the Judiciary
United States Senate

July 26, 2005

Mr. Chairman and Members of the Subcommittee:

I am honored to be able to appear before the Subcommittee today to discuss international patent harmonization — a topic of great importance to innovation in the United States and Worldwide.

I have been an advocate of enhanced international cooperation in the patent area for a long time. When I was serving as Commissioner of Patents and Trademarks during President Reagan's Administration, I was appointed by the President as U.S. Ambassador to the Diplomatic Conference in the Revision of the Paris Convention. That nineteenth-century convention is the grandparent of all subsequent multinational treaties in the patent field. At that time also, I was elected by the member states of the United Nations World Intellectual Property Organization ("WIPO") to be the Chairman of the WIPO General Assembly. In 1983, I was pleased to be a founder of the "Trilateral Cooperation Agreement" among the European Patent Office ("EPO"), the Japan Patent Office ("JPO") and the U.S. Patent and Trademark Office ("USPTO). I currently teach seminars at both

the George Washington University Law School and the George Mason University School of Law on Multinational Protection of Intellectual Property.

I should note that in my testimony today, I am not speaking for either the Oblon, Spivak law firm or those two law schools.

There is a debilitating redundancy built into the current national/regional patent search, examination and enforcement systems. With respect to any important invention, highly skilled patent examiners around the world X most of whom are scientists or engineers and many of whom in addition, particularly in the United States, have legal training X analyze the *same* patent application, search the *same* prior art, and perform the *same* examination before granting virtually identical patents in their respective jurisdictions. Once granted, a patent must be enforced individually in each individual jurisdiction. This unnecessary redundancy drives up the costs of obtaining and enforcing world-wide patent protection to a level that can only be afforded by the largest multinational corporations. Some time ago, the senior patent counsel of one of the world=s major research-based pharmaceutical companies estimated, for example, that it costs between $750,000 and $1,000,000 to obtain comprehensive world-wide patent protection for an important chemical compound, and that figure is growing at a rate of 10% each year. The costly duplication of effort also adversely impacts the governments themselves, many of which are looking for ways to reduce the costs associated with patent protection within fixed or in many cases reduced resources.

Figure 1 is an analysis done by the JPO of the cross-border flow of patent applications among Japan, Europe and the United States last year. It does not include patent applications filed with individual member countries of the European Patent Convention. During 2004, a total of 210,000 patent applications crossed the borders separating the three "Trilateral" areas.

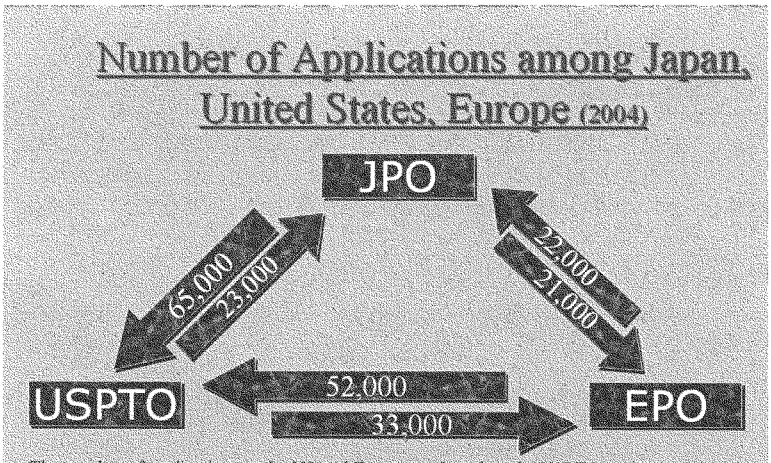

Figure 1

A total of more than 940,000 patent applications were filed last year in the JPO, the EPO and the USPTO. Each of those offices faces major challenges to keep the time it takes to examine an application within acceptable limits.

An initial effort to achieve deep harmonization of patent laws within the WIPO was cut short in 1997 when then-Secretary of Commerce, the Honorable Ronald H. Brown, informed the WIPO that while "other international negotiations continue, [the United States] will maintain our first-to-invent system, while keeping open the option of full patent harmonization in the future." The result was agreement on The Patent Law Treaty —a useful *procedural* agreement that falls short of substantive harmonization. Recent efforts of the WIPO Standing Committee on Patent Law, working on a Substantive Patent Law Treaty ("SPLT"), have not fared much better, largely as the result of a few developing countries trying to use that forum to roll back the progress made in the landmark TRIPS accord.

Currently, the hopes for substantive patent harmonization hinge on the efforts of a number of countries that signed a Statement of Intent at an Exploratory Meeting of Interested Parties Concerning the Future of Substantive Patent Law Harmonization held February 3-4, 2005, in Alexandria, Virginia. That meeting was followed by a meeting in April at the EPO, to be followed, in turn, by meetings at the JPO and the USPTO.

I have attached to my statement an article that I coauthored in 1998 entitled World Patent System Circa 20XX A.D.[1] In that article, my coauthor, Ms. Vivian Kuo, and I (1) trace the successful efforts of the past two or three decades to move from purely national patent systems to multinational regional systems, (2) outline a vision of what an efficient and effective World Patent System might look like, (3) identify the issues and challenges

[1] *World Patent System: Circa 20XX A.D.*, 38 IDEA 529 (Franklin Pierce Law Center 1998), reprinted in 80 Journal of the Patent & Trademark Office Society 523 (1998) and in 31 Intellectual Property Law Review 3 (West Group 1999)

to be resolved on the way to a global or World Patent System, and (4) describe the steps now being taken in Japan, Europe and the United States to move beyond the current national and regional patent systems.

Although there are many aspects to deep patent law harmonization, none is more important, in my opinion, than the United States moving to a first-inventor-to-file system of priority. At the end of 1997, there were two nations that used the so-called first-to-invent system: the United States and the Philippines. Effective January 1, 1998, under its Republic Act No. 8293, the Philippines adopted a first-to-file system, leaving the United States alone in the world in adhering to a first-to-invent system.

Patent examiners worldwide examine an inventor's claims — his/her definition of the invention — against what patent professionals call "prior art" — i.e., earlier work of others. As long as the United States alone in the world adheres to a first-to-invent system of priority, there can be no realistic expectation that a universally agreed upon definition of prior art can be achieved. Thus, from an international harmonization point of view, nothing in H.R. 2795 is as important as Section 3 of the bill that would establish a first-inventor-to-file priority system.[2] As long as the United States adheres to a first-to invent system of priority, international discussions of deep patent harmonization will remain hypothetical or theoretical.

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[2] As early as 1965, a major Presidential Commission studying the United States patent system strongly recommended that the United States adopt the otherwise universal first-to-file system. "To Promote the Progress of... Useful Arts in an Age of Exploding Technology," Report of the President's Commission on the Patent System, Washington, D.C. (1966). This is not a partisan matter. The 1966 Commission Report was to President Johnson. In August 1992, the Advisory Commission on Patent Law Reform reached virtually identical conclusions in its report to the Secretary of Commerce in the Bush Administration. The Advisory Commission on Patent Law Reform, Report to the Secretary of Commerce (Aug. 1992).

An argument is sometimes heard that adopting the universal first-inventor-to-file rule would somehow disadvantage independent inventors and small businesses — two classes of extremely important and productive users of the U.S. patent system. Twenty-two years of experience indicates that the United States first-to-invent system of priority has provided no advantage to small entities. Actually, the opposite is true: more small entities were disadvantaged by the first-to-invent rule than were advantaged.

To provide adequate funding for the USPTO, I recommended in 1981 to the Secretary of Commerce and he in turn recommended to the President through the Office of Management and Budget (1) that the user fees for patents and trademarks be substantially increased and (2) that the USPTO be able to use the increased fees to fund its operations instead of those fees being deposited in the miscellaneous receipts of the U.S. Treasury. That recommendation was sent to the Congress in connection with the Administration's FY 1983 Budget, and, acting on a bill introduced by Senator Hatch, Congress enacted it in P.L. 97-247.

A key part of the statutory patent fee structure enacted at that time was that it established a two-tier fee system that we had recommended. That two-tier fee system allows qualifying independent inventors, small businesses and nonprofit institutions — referred to collectively as "small entities" — to pay half of the standard patent filing fees, patent issue fees and patent maintenance fees.[3]

[3] 35 U.S.C. § 41, 37 C.F.R. §§ 1.16 et seq.

Thus, since fiscal year 1983, the USPTO has been able to keep track statistically of all patent applications that it receives and of all patents that it grants by four categories: (1) independent inventors, (2) small businesses, (3) nonprofit institutions and (4) large entities. Thus, we have 22 years of actual data on what happened to small entities when they are forced to prove that they were the first-to-invent in an arcane and burdensome complex of substantive and procedural rules and regulations governing what are called "interferences" in the USPTO.

First, let me define terms. In this statement . . .

- I will say that a small entity was *advantaged* by the first-to-invent system if the small entity was the *junior party* in an interference — i.e., the second person to file a patent application on the invention — and received a *favorable* decision.
- I will say that a small entity was *disadvantaged* by the first-to-invent system if the small entity was the *senior party* in an interference — i.e., the first person to file a patent application on the invention — and received an *adverse* decision.

From 1983 through 2004, the USPTO received 4,500,649 utility, plant and reissue applications and granted 2,456,479 such patents. During that same period there were a total of 3,253 two-party decisions in interference cases, a tiny fraction of the applications filed and patents granted. (Figure 2.) Using the number of applications filed as the denominator, the number of two-party decisions amounted to less than one in 1,000 (0.1%) of the applications filed. Using the number of patents granted during the 22-year period as the denominator, the percentage of two-party decisions increases but is still less than two in 1,000 (0.2%) of the patents granted.

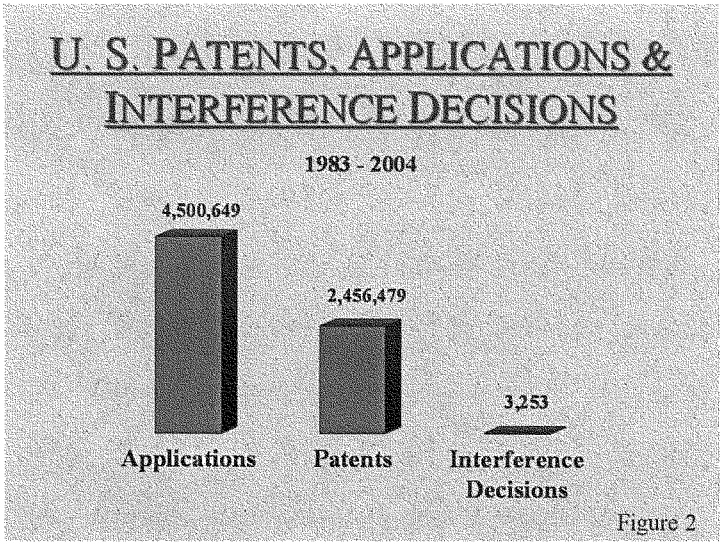

Figure 2

Based upon an analysis of the small entity data that now exists, the USPTO reports that the number of small entities that were advantaged by the first-to-invent system during the 22 years — 1983–2004 — was 286, whereas the number of small entities

disadvantaged was slightly higher, namely, 289. (Figure 3.)

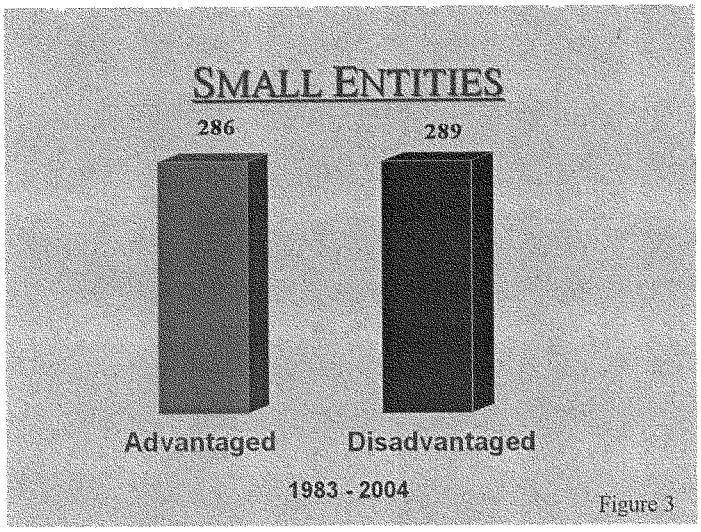

Figure 3

- 50 non-profit institutions were advantaged and 30 disadvantaged. (Figure 4.)

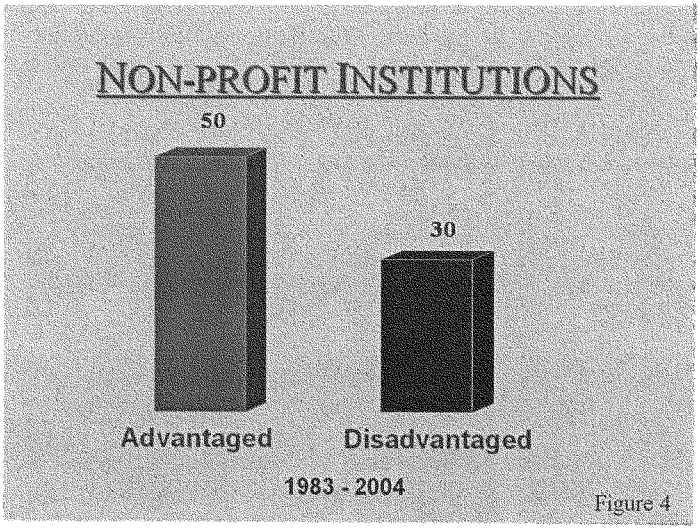

Figure 4

- 97 Small Businesses were advantaged and 92 disadvantaged. (Figure 5.)

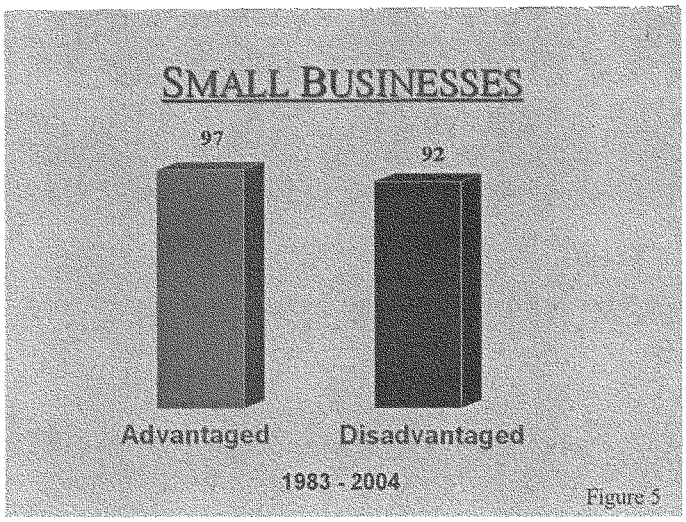

Figure 5

- 139 independent inventors were advantaged and 167 were disadvantaged. (Figure 6.)

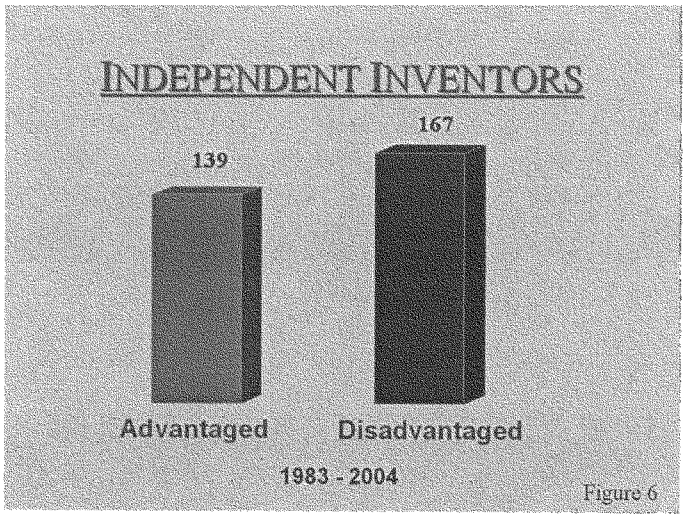

Figure 6

Figure 7 shows these data on the same scale.

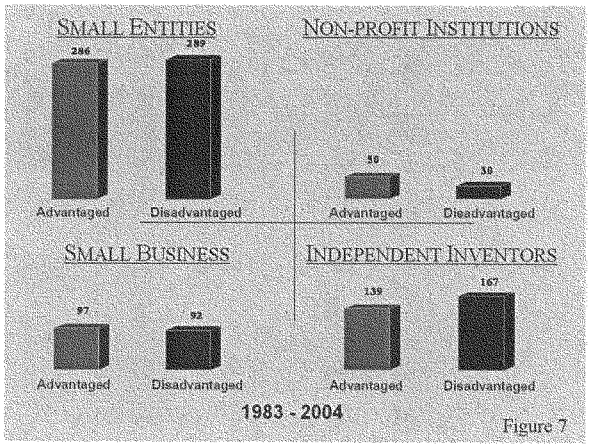

Figure 7

Those of us who believe that adopting the first-inventor-to-file system of priority in the United States would actually favor small entities point out that the current system of forcing a small entity into an interference proceeding with a large and determined company that filed a patent application *after* the small entity could cost the small entity hundreds of thousands of dollars, even if it ultimately received a favorable decision. More importantly, small entities by their very nature can move more quickly than larger bureaucracies. And here is where the United States *provisional application* comes into play. By filing a complete technical disclosure of the invention, a small entity can readily secure priority rights in a first-inventor-to-file system without a major expenditure of resources. This then gives the small entity a year in which to file a professionally prepared patent application.

Moreover, by retaining an "inventor's rights contest" in H.R. 2795 (in 35 U.S.C. § 135(a)), the bill is true to the Constitution since it would reward exclusive rights only to true inventors for their discoveries.

The data provided by the USPTO confirm empirically that the current first-to-invent system of priority provides no advantage to small entities. Figure 7 speaks for itself. Historically, virtually the same number of small entities were advantaged by the first-to-invent system (286) as were disadvantaged (289). And with respect to independent inventors — among the most vocal of first-to-invent adherents — somewhat more were disadvantaged (167) than were advantaged (139) by the first-to-invent system.

There are many good reasons why the United States should join the rest of the world in adopting a first-inventor-to-file system — reasons well beyond the scope of this statement. I hope that the data presented in this statement — based on 22 years of actual experience — will add constructively to the debate on § 3 of H.R. 2795.

Mr. Chairman, this concludes my prepared statement. I would be pleased to respond to any questions you or the other Members of the Subcommittee may have.

STATEMENT OF

CHARLES E. PHELPS
PROVOST
UNIVERSITY OF ROCHESTER

ON BEHALF OF THE

ASSOCIATION OF AMERICAN UNIVERSITIES
AMERICAN COUNCIL ON EDUCATION
ASSOCIATION OF AMERICAN MEDICAL COLLEGES
COUNCIL ON GOVERNMENTAL RELATIONS

BEFORE THE

SENATE JUDICIARY SUBCOMMITTEE ON INTELLECTUAL PROPERTY

JULY 26, 2005

Chairman Hatch, Ranking Member Leahy, and Members of the Subcommittee:

I am Charles Phelps, Provost at the University of Rochester. In addition to serving as the chief academic officer of this research university, I am a member of the Intellectual Property and Information Technology Committee of the Association of American Universities, and I am currently serving as Chairman of the Patent Reform Working Group of the Association of American Universities, the American Council on Education, the Association of American Medical Colleges, and the Council on Governmental Relations. I appreciate the opportunity to appear before this subcommittee to present the views of these four associations on harmonization of international patent laws and other issues concerning patent reform. Collectively, these associations represent the major research universities and medical colleges that conduct most of the nation's basic research.

The research conducted in our nation's universities expands the frontiers of knowledge and produces discoveries that enhance our national security, strengthen our economic competitiveness, and enrich the lives of our citizens. Basic research has brought about some of the most significant innovations that have strengthened U.S. economic competitiveness. According to Nobel Laureate economist Robert Solow, at least half of the economic growth during the past 50 years has come from innovation that has created new technologies, industries, and jobs. The World Wide Web, Magnetic Resonance Imaging (MRI), and fiber optics all grew out of basic research. University basic research has created an estimated 4,000 spin-off companies that have hired 1.1 million employees and have generated annual world sales of $232 billion.

Although the principal means by which university research results are disseminated is through peer-reviewed publications, conferences, and other forms of open communication, the nation also benefits substantially from university research through technology transfer processes where fundamental discoveries are moved into the commercial sector for development into useful products. The landmark 1980 Bayh-Dole Act, which authorized universities and small businesses to retain patent and licensing rights to inventions resulting from federally funded research, has been an extraordinarily successful mechanism for facilitating the transfer of basic discoveries into the commercial sector for development. The patent system is an integral part of this process.

Universities play a critical role in the innovation process and have a strong interest in the means by which the patent system advances this process. We welcome this opportunity to examine the role of harmonization and other reforms to U.S. patent law that will enhance the capacity of that system to support research, development, invention, and innovation in the U.S. and worldwide.

We believe that the fundamental goal of a re-examination of the U.S. patent system should be to identify policy changes that will enhance the capacity of this system to support innovation. Our comments are based on our assessments of how such reform proposals would affect the capacity of universities to carry out their fundamental mission of research and teaching and, as part of that mission, contribute effectively to the

innovation process. Our views are also shaped in significant measure by the National Research Council's report, *A Patent System for the 21st Century*. We comment here on key patent reform proposals which have been raised in recent national discussions, many of which are included in HR 2795, the "Patent Reform Act of 2005.

Harmonization: Moving to a First Inventor to File Process

Changing the U.S. patent system from a first to invent to a first inventor to file process, which was recommended by the National Research Council's report, would harmonize U.S. patent law with that of other countries to a significant degree. As both science and commerce become increasingly international, more patent owners will want their patents to apply internationally as well as domestically, and harmonizing the basis for determining application priority would increase the simplicity and reduce the cost of patent filing.

Moving to a first inventor to file process also would add greater clarity to the U.S. patent system by replacing the subjective determination of the first inventor with the objective identification of the first filer. This change would reduce or eliminate the unpredictable and often substantial costs of interferences and litigation associated with determining the first inventor.

The harmonization and clarity brought by a first inventor to file process would provide significant benefits to the U.S. patent system as well as to universities. However, other ramifications of moving to a first inventor to file process raise concerns among some members of the university community about their ability to operate effectively in such a patent system. University inventors typically are faculty members who first publish in academic journals and later consider whether to file for a patent. Before filing a patent application, universities often need time to consider the potential commercial application of a basic research discovery, which may not be obvious at the point of discovery, and to assess the receptivity within the commercial sector to licensing any resultant patent for development. Moreover, the budgetary limitations on non-profit universities often constrain the resources they can devote to rapid filing of fully developed patent applications. All such practices are accommodated in a first to invent system but could be compromised in a first inventor to file system.

If Congress elects to move to a first inventor to file system, we believe it is imperative that U.S. patent law maintain three components of the current U.S. patent system: (1) the opportunity to file provisional applications, (2) the 12-month grace period for publishing articles containing a disclosure of the invention, and (3) the provision of current U.S. patent law requiring an applicant to sign an oath that he or she is an inventor of the claimed invention.

Provisional applications: A first inventor to file process will likely place a higher premium on prompt filing of patent applications than does the current first to invent process. The provisional application procedure of the current U.S. patent code, under

which a patent applicant can file a provisional application and obtain an early filing date for the material in the provisional application, can aid in rapid filing and will be particularly important to universities operating in a first inventor to file process.

Grace period: H.R. 2795, introduced by House Judiciary Courts, the Internet and Intellectual Property Chairman Smith and nine additional co-sponsors, provides a 12-month grace period before the effective filing date of an invention, during which the publications or other disclosures made by the inventor, joint inventor or others who obtained the disclosed subject matter from the inventor or joint inventor are not treated as prior art. Such a provision encourages the early disclosure of basic research results by an inventor while permitting him or her to file up to a year later.

However, current US patent law provides a broader grace period covering the publications not only of the inventor but also of others carrying out research in the same area. We believe that such a provision facilitates research collaborations and encourages publication and other forms of disseminating research results in ways that are important within the university community and are consistent with both the operation and objectives of the patent system. A broad grace period has a beneficial effect of separating open and unfettered academic discourse from the patent filing process. Researchers are free to develop and disseminate their research results widely to advance knowledge without foreclosing the opportunity of any one of them, separately and independently of such dissemination, to pursue a patent application. Thus, the broad grace period of current law operating in a first inventor to file system would encourage open communication of research discoveries and preserve a broad opportunity for the filing of patent applications.

We recognize that such a grace period could allow another person to "scoop" an original inventor, drawing on that inventor's publication to help develop and file a patent application before the inventor does. But we believe the benefits to research collaboration and open communication encouraged by a broad grace period override such a problem.

Therefore, we recommend that Congress include the broader 12-month grace period of current law in any patent reform legislation. Moreover, the benefits of a broad grace period should not be limited to the United States: , we urge Congress to request the Administration to seek adoption by other countries of the current U.S. grace period, as recommended in the National Research Council's report. The simplification and consistency that such harmonization would bring would benefit both the United States and other countries, and it would also encourage broad dissemination of new discoveries in the increasingly international conduct of science.

Applicant oath: Current U.S. patent law requires that the individual filing an application, or on whose behalf an application is filed, must sign an oath or declaration asserting the belief that he or she is an inventor of the claimed invention. This requirement is an important procedure underscoring the importance of a government grant of a property right. The same considerations should apply in a first inventor to file system, and we

encourage Congress to include in patent reform legislation the requirement for an applicant to sign an oath asserting inventor status.

The associations recognize the benefits of a first inventor to file process and do not oppose a move to such a process. However, given the problems that could be posed for universities operating in a first inventor to file process, it would be important to maintain in any such revised patent system three provisions of current U.S. patent law—provisional applications, a broad 12-month grace period, and the signing of an oath by the applicant.

Post-Grant Opposition Procedure

The associations strongly support the creation of an administrative post-grant opposition procedure. An opposition procedure that is of finite, predictable duration and allows third parties to challenge a patent based on the full array of issues of patentability, utility, and adequacy of the written description and enablement of how to make and use the invention would improve patent quality by providing a relatively low-cost alternative to litigation to establish patent validity.

Such an opposition procedure should require that all persons requesting an opposition identify themselves and the real party in interest, if different. It is fair and appropriate that a patent holder should be able to know the identity of the party opposing the patent, and no useful purpose is served by withholding the identity of the opposer.

A 12-month window, rather than the 9-month period included in H.R. 2795, could benefit smaller entities, which may need more time to identify and respond to patents about which they have concerns. The added three months would still keep the opposition procedure within the framework of a finite, predictable process.

It will be critical, however, for the United States Patent and Trademark Office (U.S. PTO) to receive the resources necessary to implement this additional administrative procedure. Failure to do so could cause significant increases in patent pendancy, undermining the considerable benefits that an effective post-grant opposition procedure could bring to the patent system.

CREATE Act

The CREATE Act, which was enacted into law last year, was intended to facilitate research collaboration. We strongly encourage the continuation in any patent reform legislation of the properties of the CREATE Act, including its effective date and legislative history.

Continuation Applications

Continuation applications serve important purposes for universities. Particularly in some research fields such as the life sciences, where the rapid pace of discovery runs ahead of the often unavoidably slow pace of U.S. PTO processing of patent applications, continuation applications are a valuable procedure for updating applications to reflect recent developments. We understand that continuation applications have been abused in the past by some patent applicants who attempt to extend patent applications through continuations until market conditions provide an opportunity for them to have a patent issue and file an infringement suit. However, there is some evidence that the efficacy of "submarining" patents through continuation applications was substantially reduced by the enactment in 1999 of the requirement for publication of most applications after 18 months. [1] In addition, the 1995 change to a 20-year patent term measured from the date of filing rather than a 17-year term from the date of patent grant diminishes the incentives for submarining patents.

If Congress concludes that misuse of continuation applications is an ongoing problem that needs to be addressed, we hope that any legislative proposal to do so would not limit the legitimate use of continuations by universities or any other patent holder.

Prior User Rights

The associations strongly oppose proposals to expand prior user rights such as that contained in HR 2795. As a practical matter, any assertion of prior user rights vitiates the value of patents. We understand the legitimacy of commercial entities choosing to develop products under trade secret procedures as opposed to a public patent process. However, the proposal in H.R. 2795 to expand the prior user rights defense from a demonstration that an invention had been "commercially used" to a claim of "substantial preparations for commercial use" not only significantly weakens the value of patents but introduces an element of subjectivity into the patent system that many patent reform proposals are wisely seeking to eliminate.

Injunctions

The associations believe that injunctions are an important tool in the defense of patent rights. We recognize that there is considerable concern that injunctions are being abused, particularly in certain industry sectors, by some parties exploiting the issuance of injunctions by courts to extract unwarranted settlements from companies. However, the

[1] A recent Master's thesis which examined continuations of patent applications in molecular biological pathways found no evidence of submarining behavior in the applications examined after 1999, when the 18-month publication requirement for most applications was enacted. Eric M. Hoefer, An Analysis of the Effect of Patenting Research Tools on Innovation in Three Biological Research Domains: CTLA-4, NF-KB, and EGFR, Thesis for Masters in Public Policy, Duke University; on file with the author.

associations oppose statutory changes that would weaken patent rights by reducing the ability to defend those rights through the legitimate use of injunctions.

18-Month Publication

The associations support modifying U.S. patent law to require that all applications be published 18 months after their effective filing date. Currently, patent applications are published after 18 months unless an applicant requests non-publication and is not intending to file in another country that has an 18-month publication rule. As noted earlier, there is some evidence that even the current, limited 18-month publication requirement has reduced the number of submarine patents. Requiring publication of all patent applications after 18 months may well further discourage any abuse of continuation applications. In addition, requiring the publication of all applications after 18 months will further harmonize U.S. patent law with European and Japanese patent laws. But the strongest reason for requiring publication of all patent applications is its congruity with a fundamental purpose of patent law to encourage disclosure in return for limited proprietary control over one's intellectual property. Such a requirement is fully consistent with the academic mission of full and open communication of research results at the earliest feasible opportunity.

Damages

Concerns have been expressed that under current law, courts are issuing damage judgments providing excessive awards, particularly in the case of component patents. However, since judges have ample discretion under current law to assess the relative value of a patented technology in determining damages, we believe no changes to current law are needed.

Submissions by Third Parties

The associations support proposals to allow preissuance submissions by third parties. Such a provision will promote patent quality and validity by assisting patent examiners to gather all relevant evidence in evaluating patent applications.

Experimental Research Exemption

We believe that Congress should give careful consideration, in consultation with all parties with an interest in the patent system, to inclusion of an experimental research exemption in any patent reform bill that goes forward. Such an exemption should be carefully crafted to promote experimental research, while advancing the goals of the patent system and the larger society it serves, rather than any specific sector of society.

The exemption should at a minimum allow research that specifically examines the nature of a patented invention—to determine whether it functions as claimed, to better understand its operation under various conditions, to discover something unknown about it, or, under appropriate circumstances, to improve upon it. A narrowly crafted exemption for research on the functioning of a patented invention could provide a fuller understanding of a patent without threatening the market for the patent, thereby advancing the fundamental goal of the patent system to promote innovation through a combination of disclosure and proprietary protection. All European Union nations except Austria have such a research exemption; thus, adoption of such an exemption would promote harmonization.

Crafting a research exemption that advances broad societal interests without intruding into the proprietary protections intended by the patent system is a difficult process, but we believe the potential benefits to society of an appropriately developed research exemption that is congruent with the goals of the patent system warrants thorough examination. We welcome the opportunity to work with Congress and other appropriate parties to carry out such an examination.

Testimony of
Marshall C. Phelps, Jr.
Corporate Vice President and
Deputy General Counsel for Intellectual Property
Microsoft Corporation

"Patent Harmonization and Other Issues"
Before the
Subcommittee on Intellectual Property
Committee on the Judiciary
United States Senate

July 26, 2005

Chairman Hatch, Senator Leahy and members of the Subcommittee, my name is Marshall Phelps, and I am Corporate Vice President and Deputy General Counsel for Intellectual Property at Microsoft. I thank you for the opportunity to testify before you today and to provide Microsoft's views on patent harmonization and other matters impacting the patent system.

Microsoft's Perspective

Microsoft believes that our patent system is fundamentally strong, but that its long-term health could be threatened unless we take the opportunity to embrace reforms that address 21st Century challenges and realities. Through its series of hearings on the patent system and opportunities to improve it, the Subcommittee has heard testimony on patent quality, the impact of excessive litigation and the benefits of promoting international harmonization. I will address each of these areas today.

Microsoft is among the nation's largest investors in research and development, spending nearly $7 billion per year. This makes us one of the nation's largest holders of intellectual property rights and one of its leading patent filers.

Patents are a key part of Microsoft's intellectual property portfolio and that of virtually every technology company. The reasons for this are simple:

- Patents provide critical protection for distinctive technologies that are often difficult to innovate, but which could easily be replicated without the protection of a patent;
- Reflecting the way in which our industry and other industries operate and have operated for decades, patent protection encourages technology developers to license and share key technologies; and
- Patents provide a repository of accumulated knowledge that allows new generations of innovators to learn from the state of the art and design new solutions that further advance that body of knowledge.

In today's technology marketplace, customers often build systems to meet their specific needs. The ability of different products and systems to work together is essential. Patents enable technology companies to integrate systems and meet customer needs while ensuring a return on their investments and their inventions.

Promoting Patent Harmonization

Microsoft earns more than 50 percent of its revenue in overseas markets. This is not at all unusual for companies in the IT sector. The globalizing economy raises new challenges for innovators, whether large corporations, small start-ups or individual inventors.

While our business and that of a growing number of American companies is global, there is no global patent system. Inventors who desire protection in a particular country must take steps to obtain protection within that jurisdiction. The costs and barriers to access posed by a multiplicity of national patent regimes – all sharing the same basic goal, but each imposing disparate administrative burdens on inventors – is something that industry and policymakers should care deeply about. A focus on promoting international patent harmonization and greater cooperation and work-sharing among national patent authorities is key to reducing these barriers.

The U.S. patent system plays an important role in the global economy. Consider this: of the top ten recipients of U.S. patents in 2004, only four were U.S. companies. That number is actually higher than in years past. In the 1990s, it was not uncommon for only one or two of the leading patent recipients to be U.S. firms. These figures speak to the importance innovators all over the world assign to patents and patent protection and to

the importance of the U.S. market as a driver of global economic growth. They also demonstrate how important it is for the U.S. system to get it right.

In this environment, it is essential that the U.S. recognize where its system is out of step with the rest of the world. The U.S. "first-to-invent" system is an often-cited example. The United States is the only country in the world that applies a "first-to-invent" standard for establishing priority between true inventors claiming the same invention. Every other country awards the patent to the first inventor to file. In the past, some have argued that the first-to-invent system benefits small inventors and should therefore be preserved. But recent research indicates that this is not the case. Former PTO Commissioner Mossinghoff's work in this area has demonstrated that "interferences" – the U.S. Patent and Trademark Office (USPTO) procedure used when two parties claim the same invention at nearly the same time – often disadvantage small entities and can come with considerable costs. We urge the Committee to revisit this issue in light of this new and persuasive information.

In moving to the first-inventor-to-file system, however, care must be taken to avoid unnecessary changes that could impact patent quality. For example, wholesale redefinition of what constitutes prior art is not required for harmonization with a worldwide first-inventor-to-file system and could serve to increase uncertainty and diminish what is currently considered prior art.

We also endorse the proposal that USPTO publish all pending applications at 18 months after their initial filing. U.S. law already requires 18-month publication where the invention is also the subject of a foreign patent application. According to USPTO data, only 10 percent of applications currently filed are U.S.-only applications not published at 18 months. Adopting full 18-month publication will make the patent system more transparent and will complement the goals of the proposed post-grant opposition procedure.

Moving to first-inventor-to-file and full 18 month publication would significantly enhance the opportunity to make real progress toward a more global, harmonized patent system. USPTO continues to recognize the importance of progress toward international harmonization through its considerable efforts to advance substantive patent law harmonization and to promote greater cooperation among patent offices. We commend USPTO's

efforts to bring together interested international parties and to drive this work forward.

Ensuring Patent Quality at a Time of Increasing Patent Quantity

During his recent testimony before the Subcommittee, Under Secretary of Commerce for Intellectual Property Jon Dudas commented extensively on the increasing volume and complexity of USPTO's workload and on the burgeoning U.S. and international backlog of patent filings. To ensure that USPTO has the resources it needs to address the challenges before it, we believe continued adequate funding for the agency and an end to the diversion of user fees paid to the USPTO must be a priority. We believe that this, more than any other action, can help assure patent quality, and we thank the Chairman and Ranking Member for their leadership in this regard.

We also believe that persistent concerns about patent quality in the face of increasing patent quantity could be alleviated if interested parties were given sufficient opportunity to address questionable patents through appropriate and carefully structured administrative mechanisms. Currently, the primary way to challenge the validity of a patent is through costly and difficult litigation. Microsoft supports the establishment of a post-grant opposition procedure enabling third parties to challenge the validity of issued patents. Such a process would allow the USPTO to take a careful look at any challenged patent in the context of an administrative proceeding designed to augment the patent's initial examination. Similar procedures already exist in the European system and in Japan and could help weed out questionable patents before they become the subject of court actions.

We also support proposals to ensure that interested parties have sufficient opportunity to alert the USPTO to questionable patents within the USPTO review process itself. Under current law, members of the public with relevant prior art have only limited options to submit that art to the examiner. Allowing third parties to submit information regarding relevant prior art to the patent examiner during the examination process would help address concerns about a lack of adequate prior art in certain technology areas and would help harness private-sector resources in USPTO's efforts to improve patent quality.

In both instances, however, care must be taken to ensure that the procedures serve the interests of innovators and the public by safeguarding against abuses that could burden the patent office, harass applicants or delay the issuance of patents. Establishing limits on the amount and nature of prior art submitted by third parties, and ensuring that post-grant opposition procedures are promptly initiated and concluded would advance this goal.

Confronting Excessive Litigation

The IT industry, like so many others, is encountering the enormous costs of dealing with patents of questionable quality. Today, hundreds of patent infringement cases are pending against computer software and hardware companies, costing the industry hundreds of millions of dollars each year. Too many of these cases are brought by patent speculators, who do not develop, make or distribute any products, but rather look to the civil litigation system for leverage in the marketplace. Our industry is particularly vulnerable to such claims because our complex products often have hundreds of patented or patentable features contained within them.

Left unchecked, these practices stand to disrupt the activities of true innovators and impede their ability to deliver products and services to consumers. Proposals to deal with the situation have focused on ensuring that courts weigh the equities before enjoining distribution of a product with broad consumer benefit and on deterring opportunistic litigation by reining in excessive damage claims and settlement demands.

For example, it has been suggested that the criteria for establishing willful infringement ensure that a finding of willfulness hinges on the conduct of the accused infringer and not on whether lawyers for one side or the other have used the right combination of "magic words" in notice or opinion letters. We believe that punitive, triple damages should be reserved for cases of egregious conduct, such as intentional copying of a patented invention.

Another proposal has focused on ensuring that the patentee is entitled to claim damages only on the portion of the allegedly infringing product attributable to the asserted patent. Today, when a small component of a complex product or system is alleged to infringe a patent, the damage claim often seeks some portion of the value of the product as a whole. This often leads to unduly inflated verdicts or settlement demands.

And it has been suggested that Congress should repeal section 271(f) of the patent law which, in recent cases involving Microsoft, has been applied to allow U.S. damages to include copies of software made outside the U.S. where the copies are made from a master disc developed in the United States. If the software were developed outside the U.S., the rule would not apply. The rule stands to penalize companies that develop their software here and has been criticized as giving extraterritorial reach to U.S. patents.

While these problems are real and growing ones for our industry, we recognize that other industries are not as directly impacted, or are impacted differently, by patent speculators and others who would abuse the patent system. Microsoft has been working with other affected interests to explore ways to address the challenges of excessive litigation while ensuring that the system continues to function well and fairly for other sectors. We stand ready to continue to engage in those discussions.

Conclusion

Ongoing consideration of improvements has always been a part of our intellectual property system. We look forward to working with the Subcommittee in its efforts to ensure that the patent system continues to serve our nation's great interest in promoting innovation and providing the public with the benefits that innovation brings.

Thank you again for the opportunity to offer Microsoft's views in this important process.

TESTIMONY OF

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"PERSPECTIVE ON PATENTS: HARMONIZATION AND OTHER MATTERS"

BEFORE THE

SUBCOMMITTEE ON INTELLECTUAL PROPERTY, COMMITTEE ON THE JUDICIARY,
U.S. SENATE, CONGRESS OF THE UNITED STATES

JULY 26, 2005

INTRODUCTION

Chairman Hatch, Ranking Member Leahy, and members of the Subcommittee, my name is Christine Siwik and I am a partner at Rakoczy Molino Mazzochi Siwik LLP. I am pleased to testify today about these important patent-related issues on behalf of Barr Laboratories, Inc.

Barr is a generic pharmaceutical company that develops, manufactures, and markets prescription pharmaceuticals. The Company's product portfolio includes more than 100 generic pharmaceutical products in core therapeutic categories, including female healthcare, oncology, cardiovascular, anti-infective, and psychotherapeutic pharmaceuticals. Barr is a founding member of America's generic industry, and a founding member of the Generic Pharmaceutical Association, the generic industry's trade association.

As a generic drug company, Barr utilizes the abbreviated new drug application procedures detailed in the ground-breaking Hatch-Waxman legislation of 1984 in order to bring generic products to market. In some cases, Barr invokes the procedure that Congress established for challenging suspect and overbroad drug patents – patents that provide monopoly price protection for drugs that should be subject to immediate generic competition. Through its efforts, Barr has brought numerous lower-priced generic versions of life-saving drugs to market years earlier than would otherwise have been possible. Barr, for example, saved the American public literally billions of dollars by bringing a generic Prozac® product to market at least two years before the brand company's invalid patent would have expired. Barr did so after spending millions to develop its generic product, and after spending years litigating the invalidity of the brand company's patent, which, as part of that legal team, I can tell you was no easy feat given the brand's resources. And earlier this month Barr also launched a less-expensive generic version of the drug DDAVP® after the district court found the brand company's patent to be unenforceable due to misconduct before the Patent and Trademark Office (PTO).

As a company that must deal with patents in order to compete, Barr is particularly interested in Congress' look at possible Patent Act reform legislation. Any change to the Patent Act could have a profound impact on Barr's business, and could undermine the ability of consumers and taxpayers to continue to have access to the quality and affordable generic medicines upon which they have come to rely.

EXECUTIVE SUMMARY

Today, I would like to address the following points on Barr's behalf:

First, any attempt to improve patent quality should start with the PTO. At present, several aspects of PTO policy and procedure foster the issuance of patents without regard to their quality. For example, the current system for compensating patent examiners, which rewards those who issue a large number of patents and punishes examiners who do not meet their production goals, is counter-productive. Instead, examiners should be encouraged to focus on the quality, and not the quantity, of patents issued. Until such basic issues at the PTO

level are addressed, Congress should move cautiously when it comes to possible Patent Act reform legislation. This is a sentiment voiced by many who work daily with the patent laws, including, we understand, some federal judges.

Second, harmonizing U.S. and international patent law might well be a laudable goal in theory, but it could prove extremely problematic in practice. Care must be taken to ensure that any change that Congress makes strikes the right balance between encouraging innovation, on the one hand, and limiting competition, which necessarily flows from the patent grant, on the other. Harmonization should not be used as an excuse to undermine successful federal statutes, including the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, which has saved taxpayers and consumers billions of dollars and has become an essential component of our health care system.

Third, if Congress does pursue Patent Act reform, such legislation should strengthen, and not weaken, the standards for determining patentability. Simply put, making it easier to obtain and maintain a patent will not improve patent quality. Today, some brand companies have erected seemingly insurmountable patent barriers around their products. For instance, one product on which Barr currently is working has over 200 patents, which translates into nearly four decades of patent protection for that drug. Instead of addressing abuses of the patent system, provisions in H.R. 2795 relax the patentability requirements, making it even easier for brand companies to obtain and successfully enforce dubious and overbroad drug patents.

Congress should be clear about the consequences of enacting such proposals: the public will pay more, likely much more, for prescription drugs. For example, more patents means longer patent monopolies, and that could add billions to the cost of the prescription drug benefit set to begin in 2006 under the Medicare Modernization Act (MMA). According to one source, the Medicare prescription drug benefit is expected to account for roughly forty percent of all prescriptions dispensed in the United States as of January 1, 2006. The House Appropriations/Labor, HHS & Education Subcommittee has budgeted the prescription drug benefit at $53.6 billion for just the first nine months. According to a CMS analysis prepared for the Bush Administration's fiscal year 2006 budget, CMS projects payments to Medicare drug plans to total $1.2 trillion over the 10-year budget window beginning in October 2005. While CMS expects the net costs to the federal government to be smaller, it still estimates the 10-year total for federal spending on the drug benefit to be $724 billion.

Fourth, any patent reform legislation should include provisions designed to eliminate some of the unjustifiable advantages that the case law currently bestows on patentees. Over the years, the courts have created several presumptions and imposed certain burdens on alleged patent infringers that cannot be justified under the Patent Act. These inequities should be remedied.

Finally, if Congress does enact patent reform, close attention should be paid when implementing any such legislation. Specifically, the effective dates of any changes should not upset the settled expectations of regulated industry, or on-going litigation. Effective date

provisions such as those found in H.R. 2795 could have immediate, negative consequences for generic drug companies and the public.

DISCUSSION

I. Efforts To Improve Patent Quality Should Start At The PTO, With Major Changes To The Patent Act Being Broached Cautiously.

Any effort to improve patent quality should start at the PTO. As the U.S. Court of Appeals for the Federal Circuit recently reiterated, the entire patent system relies primarily on the PTO to screen out invalid patents:

> [W]e are mindful that if an invalid patent is issued, competitors may be deterred from challenging it by the substantial cost of litigation. Even if a successful challenge is brought, competition may be suppressed during the pendency of the litigation. The risk of antitrust liability or litigation sanctions may deter some from seeking to secure or enforce invalid patents, but *our patent system depends primarily on the Patent and Trademark Office's ("PTO's") care in screening out invalid patents during prosecution.*

Prima Tek II, L.L.C. v. Polypap, S.A.R.L., – F.3d –, No. 04-1411, 2005 WL 1459332 (Fed. Cir. June 22, 2005) (emphasis added).

While patent examiners no doubt strive to issue patents only on those applications satisfying the statutory criteria for patentability, some aspects of PTO policy and procedure foster the issuance of patents irrespective of quality. The system for compensating patent examiners, for example, rewards those who issue a large number of patents and punishes those who do not meet established production goals.

As Barr understands it, patent examiners are salaried employees paid pursuant to a special patent examiner GS pay scale. An examiner can, however, receive several types of monetary performance bonuses if he or she exceeds the established production goal and/or meets certain timeliness requirements. Generally speaking, the PTO calculates the production goal that an examiner must meet by considering a variety of factors, such as the difficulty of technology and length of the applications that the examiner reviews. The production goal typically is expressed in terms of the number of "counts" that the examiner must accumulate. An examiner receives two counts for each application. The examiner receives one count for sending out the first office action on an application. The examiner receives a second count for that patent application by disposing of it in one of the following ways: by allowing the patent, by abandonment of the application by the applicant, or by completing an Examiner's Answer in the appeal process. The examiner receives *no* counts for rejecting an application in a final office action, in second or subsequent non-final office actions, or in similar scenarios.

The PTO meticulously analyzes each examiner's count total every two weeks, with supervisors following up with any examiner that fails to meet his or her required count quota during that two-week period. The pressure on examiners to meet their count quota is substantial and constant. An examiner who exceeds his or her production goal for the fiscal year

is eligible for a monetary reward in the form of a performance bonus. It is Barr's understanding that those performance bonuses can reach 9% of base salary, with additional bonuses possible when an examiner meets a timeliness goal for two consecutive quarters. Equally as important, however, an examiner that fails to meet his or her production goal can be penalized. Failure to meet the assigned count quota for an entire quarter could, based upon the information we have received, result in an examiner being placed on probation, which can lead to the examiner losing his or her job. As a result, it is critically important for examiners to meet their count quotas.

The PTO compensation system thus encourages examiners to allow patents in order to receive increased performance bonuses and to avoid penalization, irrespective of the quality of those patents. Changing the system in a way that eliminates any incentive to issue questionable patents, Barr believes, would go far toward increasing the quality of patents. Others, including the Executive Director of the Public Patent Foundation, also have raised the need for reforms within the PTO in order to improve patent quality.

Finally, until the issues within the PTO are adequately addressed, Congress should approach any sweeping changes to the Patent Act carefully, and with a full understanding of how those changes would impact industries such as the generic drug industry. Barr, in fact, is not the first to raise concerns about moving too quickly in this area. For instance, speaking at the National Academy of Sciences and the American Intellectual Property Law Association, a panel of federal judges recently suggested that Congress should proceed slowly, adding that more review is needed before moving forward with the types of changes contained in H.R. 2795. According to published reports, Judge Pauline Newman of the U.S. Court of Appeals for the Federal Circuit expressed the opinion that Congress and industry need to carefully examine the impact of the bill on a broad national and global scale before moving forward with H.R. 2795. The reason for such caution is simple: Patent rights play an important role in many, many industries and drastic changes to the Patent Act, such as those proposed in H.R. 2795, could have far-reaching, negative consequences for those industries and the public. Such legislation likely would hurt the generic pharmaceutical industry – an industry already struggling to cope with brand tactics like authorized generics, which create a significant disincentive to invest in the lower-priced products needed to help ease the skyrocketing costs of health care in America.

II. Relaxing The Requirements For Patentability, Even If Done In The Name Of Harmonization, Will Not Improve Patent Quality, But Will Increase The Cost Of Prescription Drugs.

In 1984, Congress enacted the Hatch-Waxman Amendments, in part, to increase the public's access to lower-priced generic alternatives. In the words of the U.S. Court of Appeals for the D.C. Circuit, Congress' goal was to "get generic drugs into the hands of patients at reasonable prices – fast." *In re Barr Labs.*, 930 F.2d 72, 76 (D.C. Cir. 1991). In designing this important legislation, Congress recognized that if generic drug companies waited for all of the patents protecting brand-name drugs to expire before marketing a lower-priced drug alternative, the public could be forced to pay monopoly drug prices for decades.

Today, unlike in 1984, brand companies routinely obtain patent after patent on a single drug product. A majority of these patents contribute little, if anything, by way of

technological advancement. Instead, these generic-blocking patents serve as part of a litigation strategy designed to make it as difficult, costly, and time-consuming as possible for generic companies to enter the market. For example, on a product that Barr currently is pursuing, the innovator drug company has obtained over *200 patents* relating in some way to this single drug product. The first patent, covering the actual drug compound, issued in 1983. At present, the term of the latest-expiring patent related to this drug ends *38 years later*, in 2021. Let's put that in perspective – after reviewing a patent portfolio on the drug in Prozac®, the Federal Circuit declared it "a progeny of divisional applications, continuation applications, and patents that rivals the Hapsburg legacy." *Eli Lilly and Co. v. Barr Labs., Inc.*, 222 F.3d 973 (Fed. Cir. 2000). That portfolio involved just six patents. One can only imagine how the Federal Circuit would describe a portfolio consisting of over 200 patents, and this innovator company might not yet be finished obtaining patents on this drug. One thing does seem clear, though, the sheer number of patents surrounding this product likely explains why no company, other than Barr, currently is seeking to market a generic version of this product – a product that generated over $700 million in sales for the 12-month period ending May 2005, according to IMS Health – before expiration of the Orange Book patents.

Given today's realities, challenging suspect drug patents plays an even more important and necessary role in helping to contain healthcare costs. As a result, any changes to the Patent Act must strengthen the requirements for patentability. At the very least, such changes should not relax the patentability standards. Indeed, making it easier for brand companies to get patents, and harder for generic companies to avoid them, threatens to undo much of the tremendous good that Congress accomplished with Hatch-Waxman, and the subsequent MMA provisions. To be clear: Loosening the patentability standards, even if done in the name of harmonization, would create longer patent monopolies on brand-name drugs. This, in turn, keeps the price of brand-name products higher for longer periods of time, and delayed marketing of generic drugs will cost the public billions of dollars.

Moreover, relaxing the patentability requirements, by eliminating and weakening existing defenses to patent infringement claims, obviously would *not* improve patent quality. Indeed, loosening the patentability standards would have the exact opposite effect – making it easier for companies to obtain dubious patents and more difficult for companies to have such patents set aside.

Many of the proposals in H.R. 2795 exemplify the type of provisions that should be avoided. The bill relaxes patentability standards by, *inter alia*, eliminating current requirements for obtaining and maintaining a patent, and weakening other patentability requirements. In these important respects, H.R. 2795 works against enhanced patent quality.

A. H.R. 2795 Makes It Easier To Obtain And Maintain Suspect And Overbroad Patents.

H.R. 2795 would make it easier to obtain and maintain suspect and overbroad patents by eliminating: (1) the requirement that patentees act with good faith when prosecuting patents before the PTO; (2) the best mode requirement of 35 U.S.C. § 112; and (3) several of the novelty requirements found in current 35 U.S.C. § 102. Such changes, if enacted, would have

negative, real-life consequences for those that must defend against unwarranted patent infringement claims in order to compete.

Unenforceability. Section 5(a) of H.R. 2795 would represent a drastic and negative shift in the law. Under proposed § 136(d), one or more claims of the patent-in-suit must be declared invalid *before* a claim of unenforceability could be made. By making an invalidity finding a prerequisite to an unenforceability claim, the bill removes inequitable conduct as an independent defense to infringement. As a result, patentees arguably could outright lie to the PTO without having the patent declared unenforceable, so long as the patent otherwise is valid. Plainly, rewarding such misconduct before the PTO would not improve the quality of patents.

Allowing patentees to fraudulently obtain patents from the PTO and enforce those patents, so long as they otherwise are valid, would have dramatic consequences for consumers. For example, in just the last eighteen months, patents in *seven* pharmaceutical-related cases were struck down solely on unenforceability grounds due to patentee misconduct before the PTO, including:

- *Purdue Pharma, L.P. v. Endo Pharms. Inc.*, Nos. 00-8029, 01-2109, and 01-8177, 2004 WL 26523 (S.D.N.Y. Jan 5, 2004), *aff'd*, – F.3d – , 2005 WL 1330933 (Fed. Cir. June 7, 2005), which involved an attempt to market a generic version of OxyContin®. Purdue told the PTO that it had "surprisingly discovered" that oxycodone required a reduced dosage form as compared to other comparable drugs. 2004 WL 26523, at *21. Purdue failed to tell the PTO, however, that it had absolutely "no scientific proof" to back up its claim. *Id.* Purdue had conducted no testing that would support this result at the time it made this representation that was "of extreme clinical importance" and on which it heavily relied to distinguish its invention from the prior art and to ultimately obtain its patents. *Id.* at *23. The court struck down the patents on unenforceability grounds based upon the patentee's misconduct. Yet, Purdue Pharma's lawsuit kept Endo off the market for nearly three years – years during which Purdue Pharma generated billions of dollars in sales with its unenforceable patent.

- *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, No. 03887 RT, slip op. (C.D. Cal. June 15, 2005), which involved an attempt to market a generic version of Lovenox®. The PTO examiner rejected the proposed claims as obvious over the prior art. *See id.* at 9-13. In response, the patentee repeatedly represented that its data showed that the half-life of its drug was improved over the prior art. *See id.* The patentee failed to disclose to the patent examiner, however, that its data compared different dosages of the drugs, and that a comparison of the drugs at the same dosages did not result in significantly different half-lives. *See id.* at 13-14. In its opinion, the court rejected Aventis' argument that the representations were immaterial because the patent examiner allegedly did not rely on these representations in allowing the claims, explaining that, according to the law, information is material if it is in the realm of the examiner's consideration. *See id.* at 17-18. The court struck down the patent on unenforceability grounds based upon the patentee's misconduct.

- *Ferring B.V. v. Barr Labs*, No. 7:02-CV-9851, 2005 WL 437981 (S.D.N.Y. Feb. 7, 2005), which involved an attempt to market a generic version of DDAVP®. During patent prosecution, the PTO asked the patent applicant to provide objective, "non-inventor testimony" supporting the inventor's understanding of a term in the patent application. *See id.* at *9. Instead, Ferring provided affidavits from a former employee of the company, and two Ferring consultants who had received research money from Ferring. *See id.* at *3-*5. Ferring never disclosed to the PTO the three affiants' affiliations to Ferring, despite "the very clear understanding of Ferring that the PTO was interested in receiving non-inventor testimony, which, again, had to have indicated that an objective perspective was sought." *See id.* at *9. The court struck down the patent on unenforceability grounds based upon the patentee's misconduct.

- *Pharmacia Corp. v. Par Pharm.*, No. 01-6011 (D.N.J. July 6, 2004), which involved an attempt to market a generic version of Xalatan®. During prosecution of a patent-in-suit, the patent applicant submitted a false declaration. The declarant made claims about the efficacy of a drug that were exactly the opposite of the claims that he had made in an article that he had authored. *See id.* at 25-27. The court struck down the patent on unenforceability grounds based upon the patentee's misconduct.

These pro-consumer decisions, and others like them, would not be possible if H.R. 2795 is enacted as currently written because alleged infringers could no longer raise unenforceability as an independent defense. Such a result would be devastating for consumers, who would be forced to pay unnecessarily high prices for drugs protected by ill-gotten patents.

The bill also could be construed as eliminating yet another independent defense to patent infringement claims – patent misuse. If a court finds that a patentee has misused a patent, the court will declare the patent unenforceable. Thus, the defense of patent misuse focuses on the patentee's behavior *after* obtaining the patent, while inequitable conduct focuses on the patentee's behavior before the PTO. But some might argue that H.R. 2795 could be construed as requiring *all* claims of unenforceability to be pursued pursuant to the terms of proposed § 136. If so construed, the bill possibly could do away with the patent misuse defense because proposed § 136 arguably contains no mechanism for asserting or otherwise pursuing a patent misuse claim (as opposed to an inequitable conduct claim).

Moreover, the scheme that the bill would impose for addressing inequitable conduct claims virtually guarantees that patents would rarely, if ever, be found to be unenforceable. Consider just these few examples:

- The bill would establish a nearly impossible-to-meet standard for proving a violation of the duty of candor. Specifically, H.R. 2795 arguably eliminates the Federal Circuit's sliding-scale standard for determining whether a patentee has committed inequitable conduct. Under current law, the more material the withheld information, the less intent to deceive that the challenger need show. Proposed § 136(b) requires all misconduct to

have been done "knowingly." But the courts repeatedly have recognized that direct evidence of a knowing intent to deceive rarely exists.

- Under current law, a breach of the duty of candor by anyone deemed to have substantially participated in prosecuting the patent will render that patent unenforceable. But proposed § 136(d)(1) and (d)(3) would require the patent owner itself to have violated the duty of candor before a patent could be held unenforceable. This means that a patent attorney for a brand company arguably could withhold material prior art with an intent to deceive without such misconduct leading to an unenforceability finding. But deceit before the PTO, regardless of its origin, equally infects the patent and should render it unenforceable.

- Under proposed § 136(d)(2), once a patent claim has been declared invalid, the defendant must seek leave of court to amend the pleadings to include an inequitable conduct charge. If the court grants the motion, the court remits the charge to the PTO to determine whether inequitable conduct occurred. But the alleged infringer must plead its claim with particularity, which could be problematic because courts sometimes are reluctant to allow discovery on defenses that have not been pled. Because the accused infringer cannot plead inequitable conduct until after a finding of invalidity, the bill could prevent parties from getting the discovery that they might need to establish this defense with enough specificity to have it referred to the PTO.

- The bill would require the PTO to establish a "special office" to investigate these types of claims. (Proposed § 136(e)). Such an office sounds similar the PTO's so-called "fraud squad," which investigated allegations of misconduct in the 1980s. The PTO disbanded the fraud squad, leaving the courts to address inequitable conduct claims, because the situation proved unmanageable at the PTO level. For example, Harry Manbeck, the PTO Commissioner from 1990 to 1992, explained: "[T]he PTO found itself having considerable difficulty evaluating alleged violations of the duty of disclosure requirement." H.F. Manbeck, *The Evolution and Issue of New Rule 56*, 20 AIPLA Q.J. 136, 139 (1992).

- The bill appears to contemplate an *ex parte* process where only the patentee can participate. Such a process makes unenforceability findings even less likely, as the *ex parte* nature of the patent process likely allowed the original fraud to go undiscovered, and would put the federal government in the inexplicable position of rewarding, rather than punishing, those who engage in misconduct and fraud. Further, the party submitting the challenge to the PTO has no recourse if, at any point in the process, the PTO elects not to proceed with the investigation, or concludes that no inequitable conduct was committed. In contrast, the patentee can appeal any adverse decision up multiple levels of review.

Finally, the penalty provisions are weak, ensuring that they will not deter misconduct when it comes to pharmaceutical patents. Under proposed § 136(e)(6), at most, a patentee would face a $5,000,000 fine per act of misconduct. This fine pales in comparison to the revenues that an improperly obtained patent could generate for the brand company. Indeed,

many drugs generate sales in excess of $1,000,000 *per day*. Purdue Pharma's OxyContin® product, for example, generated sales exceeding *$5,000,000 per day* during the 12-month period ending May 2005, according to IMS Health data. Equally distressing is the fact that if the court found fewer than all of the patent's claims to be invalid, it appears as though H.R. 2795 would allow the patentee to continue asserting those valid claims against alleged infringers, even if the PTO finds misconduct to have occurred, so long as the patentee timely pays any fine that the PTO imposes.

Given the dire consequences that could result from such provisions, Congress should carefully consider whether harmonization and harmonization alone provides sufficient justification for enacting this type of legislation. In Barr's view, the answer is a resounding "no." The U.S. patent laws should not countenance, let alone encourage and reward, misconduct before the PTO.

Best Mode. Section 4(d)(1)(B) of H.R. 2795 would relax the patentability requirements by eliminating entirely the so-called "best mode" requirement. Currently, under 35 U.S.C. § 112, the patentee must disclose the best way, or mode, of carrying out the claimed invention. Failure to do so renders a patent invalid, and courts do, in fact, strike down patents in light of best mode violations. But H.R. 2795 allows companies to obtain valid patents even if they decide for strategic and/or commercial reasons to keep the best mode of carrying out the claimed invention a secret. Such a measure would not improve patent quality.

Some have suggested that removing this requirement can be justified on harmonization grounds. But this is a situation where Congress needs to weigh carefully whether harmonization *per se* provides a sufficient excuse for jettisoning this fundamental patent law principle.

The best mode requirement of § 112 is part of the foundation upon which the Patent Act rests. Patents, by their very nature, involve the public disclosure of a novel invention. *See Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 477-78 (1974). Indeed, that is the "bargain" that the patent law strikes – the patentee receives a period of exclusivity in exchange for complete disclosure of the invention to the public. *See id.* at 489; *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989). In other words, the public suffers monopoly prices for a limited period of time in exchange for complete disclosure of the claimed invention and the right to use that invention once the patent expires. The best mode requirement ensures that patentees live up to their end of the deal. *See Teleflex Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1330 (Fed. Cir. 2002). Thus, without the best mode requirement, the public is deprived of the benefit of the bargain that the patent laws are supposed to strike. Patentees get exclusivity, but the public does not get all of the information needed to practice that invention once the patent expires. This represents a significant loss for the public.

Furthermore, the elimination of the best mode requirement could have a particularly profound impact on efforts to develop generic biologics. In short, companies developing such products rely, often times heavily, upon the disclosures in brand patents to assist them in their development efforts. This disclosure is, after all, for the benefit of others to use as part of the bargain that the patentee makes for receiving the right to exclude accompanying the

patent grant. If brand companies no longer need to disclose their best mode in such patents, generic companies will lose a valuable source of information, even though the brand companies will continue to enjoy the full monopoly benefits provided by their patents. The public necessarily suffers in this case, especially given the fact that biologics represent a major part of health care expenditures in the United States each year.

In 2003, as Barr understands it, just six biologic pharmaceutical products generated sales of more than $9.5 billion. Three of the top biotech pharmaceuticals can cost as much as $24,000, $10,000 and $20,000 per patient, per year.[1] Another product, a biologic drug approved for an enzyme deficiency, costs over $170,000 per patient per year.[2] Generic competition would ensure increased access and lower prices. Measures that make it more difficult for generics to enter the market ensure less access and unnecessarily high prices. Thus, fundamental fairness, the core principles of the Patent Act, and plain common sense all cry out for the best mode requirement to remain in § 112.

Eliminated Novelty Requirements Of § 102. Section 3(d) of H.R. 2795 also would relax the current patentability requirements by eliminating the novelty requirements found in 35 U.S.C. §§ 102(c), (d), (f), and, arguably, (g). These provisions purportedly would be eliminated as a result of the bill's adoption of a "first-inventor-to-file" patent system – a change being considered as part of a harmonization effort.

Even if Congress decides to harmonize U.S. patent law by adopting a first-inventor-to-file system, caution should be taken to avoid doing unnecessary violence to existing patentability requirements and infringement defenses. Legislation that eliminates current § 102(g)'s prior invention requirement/defense, for example, could be particularly troublesome for generic drug companies if corrective measures are not taken.

Some generic companies have started to obtain and enforce patents against fellow generic competitors. Companies without their own drug product also have started to get patents on lucrative drug products in the hope of using such patents to obtain quick cash settlements from generic companies attempting to enter the market. A company tried this approach when it obtained patents relating to the drug fluoxetine (Prozac®) years *after* Barr filed the first ANDA seeking to launch a generic fluoxetine product. That company asserted one of its patents against Barr the day that Barr obtained FDA approval to market its product.

The prior invention defense in current § 102(g) can provide defendants in such suits with a vital invalidity defense. Indeed, the more common such suits become, the more important the defense could become. Thus, if Congress does adopt a first-inventor-to-file system, careful attention should be paid to implementing the system in a way that does not deprive alleged infringers of existing defenses to infringement claims. In the case of § 102(g), 35 U.S.C. § 273 should be strengthened to ensure that generic companies continue to have an infringement defense to these later-issued patents.

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[1] *See* DESERET NEWS, December 15, 2002 (Neupogen®, $15,000 to $24,000); ST. PETERSBURG TIMES, July 22, 2003 (Procrit®, $7,000 to $10,000; Humatrope®, $12,000 to $20,000).

[2] THE NEWS & OBSERVER, May 13, 2003 (Cerezyme®).

B. H.R. 2795 Could Severely Relax Other Patentability Requirements.

H.R. 2795 could relax, possibly severely, other patentability requirements. Of most importance is the bill's redrafting of 35 U.S.C. § 102, but Barr also is concerned about the changes that would be made to § 103. As previously explained, while adopting a first-inventor-to-file system necessarily would do away with some of the novelty requirements of § 102, Congress need not rewrite § 102 *in toto*. Indeed, several witnesses testifying before the House Judiciary Subcommittee on Court, the Internet and Intellectual Property also noted that the changes made to § 102 go well beyond those necessary to implement to first-inventor-to-file system. They cautioned against making changes that would unnecessarily diminish the scope of prior art, and would disrupt long-established legal concepts and definitions. Barr, too, urges Congress to ensure that any patent reform measures do not needlessly destroy the existing statutory scheme, and the extensive case law that has developed out of that scheme.

Changes to 35 U.S.C. § 102. In essence, the patent universe can be thought of as containing two types of subject matter: new and old. Only new subject matter can be patented. Old subject matter, often referred to as "prior art," cannot be patented. Prior art can thus be thought of as limiting or restricting what is "new" and thus patentable. H.R. 2795 re-defines prior art in a way that narrows that body of information, and anything that narrows the universe of prior art necessarily expands the universe of patentable subject matter. Accordingly, Section 3(b)(1) of the bill makes it easier for brand companies to obtain patents (even on non-inventive or old subject matter), while simultaneously making it more difficult for generic companies to successfully challenge such patents. For example, the bill arguably relaxes the current patentability requirements as relates to:

- a public use;
- a sale or offer for sale;
- foreign patents;
- foreign patent applications;
- foreign publications;
- so-called "negative" prior art (that which reaches the opposite conclusion while still teaching the invention); and
- patents or patent applications owned by or subject to an obligation of assignment to the patentee.

The anti-consumer consequences of H.R. 2795 result from several different aspects of the proposed revisions to § 102:

First, the definition of "publicly known" in proposed § 102(b) is problematic in several key respects. Proposed § 102(a)(1) talks, in part, about the invention lacking novelty if the claimed subject matter was "otherwise publicly known." Under § 102(b)(3)(A), something is "publicly known" "only when it becomes reasonably and effectively accessible, either through its use, sale, or disclosure by other means" or if "it is embodied in or otherwise inherent in subject matter that has become reasonably and effectively accessible," and for purposes of proposed § 102(b)(3)(A):

> (i) subject matter is reasonably accessible if persons of ordinary skill in the art to which the subject matter pertains are able to gain access to the subject matter without resort to undue efforts; and
>
> (ii) subject matter is effectively accessible if persons of ordinary skill in the art to which the subject matter pertains are able to comprehend the content of the subject matter without resort to undue efforts.

(Proposed § 102(b)(3)(B)). Thus, on its face, the definition of "publicly known" arguably narrows the information that otherwise would have qualified as prior art under current law. At a minimum, proposed § 102(b)(3) arguably narrows the universe of prior art presently available, thus making it easier to obtain and enforce a patent, in the following respects:

The definition of "publicly known" requires all prior art to be "reasonably and effectively accessible" such that a person of skill in the art can gain access and comprehend it "without resort to undue efforts." This represents a significant change in the law for several types of activities that currently serve to restrict what can be patented. The courts generally have not, for example, required sales, offers for sale, or the like to be "publicly known," as defined in H.R. 2795, in order to be invalidating.

- Under current § 102(b), a sale or an offer for sale can be done entirely in secret and still invalidate a patent claim. *See, e.g., Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1357 (Fed. Cir. 2001).

- Under current § 102(b), "public," in context of a public use, "does not necessarily mean open and visible in the ordinary sense; it includes any use of the claimed invention by a person other than the inventor who is under no limitation, restriction, or obligation of secrecy to the inventor." *New Railhead Mfg. Co. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1297 (Fed. Cir. 2002). Thus, "[i]t is not necessary for a product to actually be accessible to the public to fall under Section 102(b)." *System Mgmt. Arts v. Avesta Tech., Inc.*, 87 F. Supp. 2d 258, 269 (S.D.N.Y. 2000). Indeed, the Federal Circuit has expressly *rejected* a patentee's assertion that, to be invalidating, a public use must be "publicly known or accessible." *Baxter Int'l, Inc. v. COBE Labs., Inc.*, 88 F.3d 1054, 1058 (Fed. Cir. 1996). Thus, the patentee's clinical trials could constitute an invalidating "public use" under § 102. *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306 (Fed. Cir. 2004), *vacated on rehearing by*, 403 F.3d 1331 (Fed. Cir. 2005); *see also Eolas Tech. Corp. v. Microsoft Corp.*, 399 F.3d 1325 (Fed. Cir. 2005) (stating that use by a third party under no obligation to maintain the secrecy of the invention can be an invalidating public use); *but see Janssen Pharm. N.V. v. Eon Labs Mfg. Inc.*, No. 04-1539, 2005 WL 1384230 (Fed. Cir. June 13, 2005) (finding specific clinical trials did not constitute a "public use" in light of the circumstances surrounding those trials).

- Under current § 102(a), a "public" use by others merely means a "not secret" use that can take place in the usual course of producing materials for commercial use. *Levi Strauss & Co. v. Golden Trade*, No. 92-1667, 1995 WL 710822, at *18 (S.D.N.Y. Dec. 1, 1995). Consequently, the use of a patented product or process in a single shop can constitute

prior art under current § 102(a). *See Giora George Angres, Ltd. v. Tinney Beauty & Figure, Inc.*, 116 F.3d 1497 (Fed. Cir. 1997).

Additionally, the "publicly known" definition could be construed as limiting reliance on foreign patents, foreign patent applications, and/or foreign publications as prior art. For instance, if a publication or patent application exists only in a foreign language, a court could find that locating and translating such material constitutes "undue efforts," such that the publication or patent application would not constitute "prior art." This could be significant in the generic drug context, as generic companies in particular routinely rely on foreign art when arguing the invalidity of drug patents. In just the last year, courts in several pharmaceutical patent cases have found brand patents invalid in light of foreign art. And, not surprisingly, foreign art also comes into play in other subject matter areas, where courts also have struck down patents as invalid in light of foreign art.

Second, setting aside the definition of "publicly known," other aspects of proposed § 102(a)(1) will curtail the universe of information that can constitute prior art. For example, under proposed § 102(a)(1)(B), patents and printed publications by anyone who obtained "the subject matter disclosed directly or indirectly from the inventor or a joint inventor" no longer would qualify as prior art. The bill does not define what is meant by "directly or indirectly." If given a broad construction by the courts, the universe of information that can constitute "prior art" could be significantly narrowed.

Third, proposed § 102(a)(2) could have significant consequences by limiting what can be used as prior art. Under proposed § 102(b)(1), subject matter that would otherwise qualify as prior art under proposed § 102(a)(2) cannot be considered prior art if the subject matter and claimed invention are "owned by the same person or subject to an obligation of assignment to the same person." This restriction on what constitutes prior art would be particularly useful to a large, brand drug company attempting to protect generic-blocking patents from invalidity claims. For example, the Federal Circuit recently relied upon a prior art patent that the patentee had previously licensed in order to strike down a pharmaceutical patent. *See SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331 (Fed. Cir. 2005). District courts, too, recently have done so in both pharmaceutical and non-pharmaceutical cases.

Changes to 35 U.S.C. § 103. Section 3(c) of H.R. 2795 contains proposed § 102(b)(2). Under that proposal, subject matter that would otherwise qualify as prior art under proposed § 102(a)(2) cannot be considered prior art for purposes of § 103 if the claimed invention "was made by or on behalf of parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention." This change could eliminate key literature and other material as prior art.

C. By Eliminating The Requirement That Patentees And Applicants Act In Good Faith, H.R. 2795 Will Not Improve Patent Quality.

Presently, patentees can take certain actions or invoke certain procedures only if they do so with a lack of "deceptive intent." In other words, the Patent Act presently requires patentees and patent applicants to act in good faith before taking various actions or invoking

certain procedures. However, Section 5(c) of H.R. 2795 removes the lack of deceptive intent requirement from all such provisions, including in current § 116, § 256, § 184, § 185, § 251, § 253, and § 288. Precisely how patent quality will be improved by eliminating the good faith requirement from these provisions is unclear.

III. If Congress Pursues Patent Reform, Any Such Legislation Should Include Provisions Designed To Eliminate Unjustifiable Advantages That The Case Law Currently Bestows On Patentees.

Presently, the case law in some key respects is unfairly stacked in favor of patentees. If Congress decides to pursue patent reform legislation, these inequities should be remedied. Examples of unwarranted inequities include the following:

Patentees currently enjoy a statutorily-unsupported presumption with respect to certain prior art. In essence, the case law currently presumes that the PTO reviewed and expressly considered any information that the patentee submitted during prosecution. *See American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984) (observing that patent examiner is presumed to have properly done his or her job and interpreted references presented during prosecution). This presumption exists even if there is *no* evidence that the patent examiner ever fully evaluated the information. In subsequent litigation, this presumption can translate into a heightened burden of proof for the alleged infringer, which, as discussed below, already must satisfy the clear and convincing evidence standard to begin with. *See Metabolite Labs, Inc. v. Lab. Corp. of Am.*, 370 F.3d 1354, 1368 (Fed. Cir. 2004); *Al-Site Corp. v. VSI Int'l*, 174 F.3d 1308, 1323 (Fed. Cir. 1999). Nothing in the Patent Act warrants imposing any heightened burden merely because the patentee provided a copy of an article to the PTO. To remedy these inequities, Congress should consider amending the Patent Act to provide that information and references referred to during examination shall be deemed to have been considered by the PTO if, and only if, the patent examiner makes an explicit indication of the information's or a reference's scope and relevance to examination. A mere listing of information or references by the patent examiner should not be sufficient to establish that the PTO actually considered specific information or references.

Additionally, an alleged infringer currently must establish invalidity by clear and convincing evidence. But nothing in the statute itself requires this heightened showing. The mere fact that the patent is presumed valid does not, by itself, justify imposing this considerable burden. At most, the clear and convincing evidence standard should apply only when an alleged infringer attempts to establish invalidity using information or references that were expressly considered by the PTO during patent prosecution. The burden of proving invalidity of a patent based, in whole or in part, on any information or references *not* considered by the PTO should be by a preponderance of the evidence.

Further, patentees enjoy unwarranted presumptions when it comes to injunctive relief. For example, a plaintiff in any type of civil action must, generally speaking, establish four elements in order to obtain preliminary injunctive relief: a likelihood of success on the merits, irreparable harm, that the balance of hardships favors injunctive relief, and that the public would benefit from the granting of such relief. Under the current case law, however, a patentee seeking

an injunction against an alleged patent infringer often enjoys a presumption that it will suffer irreparable harm if an injunction does not issue. *See, e.g.*, *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1367-68 (Fed. Cir. 2001) (upholding the grant of a preliminary injunction preventing drug company from launching its competing product).

Barr believes that if Congress moves forward with patent reform legislation, the public interest is best served by revising 35 U.S.C. § 283 to include the following concepts:

- a preliminary or permanent injunction should not be issued unless the court finds that the patentee is likely to suffer irreparable harm that cannot be remedied by the payment of money damages; and

- the court will not presume the existence of irreparable harm, but instead will consider and weigh evidence that establishes or negates any equitable factor relevant to a determination of the existence of irreparable harm, including the extent to which the patentee makes use of the invention.

The April 2005 Committee Print of H.R. 2795 contained most of these concepts. Unfortunately, that language does not appear in the bill.

IV. If Congress Enacts Patent Reform Legislation, Caution Should Be Exercised When Implementing Such Changes.

If Congress enacts patent reform legislation, it should ensure that those changes are implemented in a way that does not upset settled expectations. For example, the effective date provisions of H.R. 2795 could, and likely would, have immediate negative consequences for industry. Among other things, Section 11(g) of the bill provides:

> (g) DETERMINING VALIDITY OF CLAIMS.—For the purpose of determining the validity of a claim in any patent or the patentability of any claim in a nonprovisional application for patent that is made before the effective date of the amendments made by section 3, other than in an action brought in a court before the date of the enactment of this Act—
>
> (1) the provisions of sections 102(c) and 102(d) of title 35, United States Code, shall be deemed to be repealed;
>
> (2) the provisions of sections 102(f) of title 35, United States Code, shall be deemed to be repealed and replaced by the provisions of section 101 of title 35, United States Code, as amended by section 4(a) of this Act, relating to the inventor's right to seek and obtain a patent, except that a claim in a patent that is otherwise valid shall not be invalidated by reason of this paragraph; and
>
> (3) the term "in public use or on sale" as used in section 102(b) of title 35, United States Code, shall be deemed to exclude the use, sale, or offer for sale of any subject matter that had not become reasonably and effectively

> accessible to persons of ordinary skill in the art to which the subject matter pertains, as defined in the amendments made by section 3 of this Act.

Enacting such a provision could be immediately harmful for at least the following reasons.

First, it upsets the settled expectations of generic drug companies, and perhaps competitors in other industries. The process for preparing a generic drug application takes years. For drugs currently under development, generic companies have reviewed the relevant patent landscape and made decisions about what drugs to pursue based upon the law as it currently stands. Section 11(g), if enacted, could significantly change that law to the detriment of those companies. For example, Section 11(g)(3) would eliminate the current law involving the public use and on-sale bar defenses of § 102(b), and replace it with "reasonably and effectively accessible" standard found in Section 3 of H.R. 2795. For the previously-discussed reasons, such a change could negatively impact generic drug companies.

Second, the provision conceivably could create situations where different patents in the same law suit are governed by different law. For example, Generic Company X currently is engaged in litigation involving several patents, but Brand Company Y has other patent applications pending in the PTO. H.R. 2795 is enacted, as written, today. The PTO grants two new patents to Brand Company Y next week. Brand Company Y adds those patents to its existing litigation against Generic Company X. The current law governs the patents issued before enactment of H.R. 2795, but Section 11(g)(3) arguably can be construed as applying to the patents issued after its enactment. If so, Generic Company X now has two sets of patents, each governed by different legal standards, in the same litigation. Such a situation plainly should be avoided, as it severely prejudices the generic company.

CONCLUSION

Thank you, Mr. Chairman, Ranking Member Leahy, and Members of the Subcommittee, for giving Barr the opportunity to explain its views and concerns about this important topic. Barr looks forward to continuing to assist Congress in this area.

SUBMISSION BY
TEVA NORTH AMERICA
ON
THE PATENT REFORM ACT OF 2005
(H.R. 2795)

Before
The Subcommittee On Intellectual Property,
Committee On the Judiciary,
United States Senate,
Congress Of the United States

August 3, 2005

INTRODUCTION

Teva North America ("Teva NA") presents the following comments on the proposed amendments to the patent statute in *The Patent Reform Act of 2005*, H.R. 2795.

Teva NA is part of the Teva group of companies, a vertically-integrated global pharmaceutical company founded in Israel in 1901. Teva NA is the second largest pharmaceutical manufacturer in the United States based on the number of prescriptions dispensed, and includes Teva Pharmaceuticals USA, Inc. ("Teva USA"), one of the largest marketers of generic drugs in the United States. Teva NA's headquarters are in North Wales, Pennsylvania. It has manufacturing facilities located in several states. With more than 230 products on the U.S. market, Teva NA manufactures approximately one out of every sixteen prescriptions dispensed in the United States. Although Teva NA is best known as the U.S. market's largest generic player, it is also a developer and manufacturer of patented, researched-based pharmaceutical products. One such product which Teva produces and markets is the leading pharmaceutical product for the treatment of multiple sclerosis. Because of its dual role, Teva has a deep appreciation for the fine balance between encouraging innovation and ensuring access to affordable medicines.

As a leading manufacturer of generic pharmaceuticals, Teva USA uses the Hatch-Waxman abbreviated new drug application (ANDA) procedures to bring generic pharmaceuticals to market. Teva USA has been and continues to be involved in many patent litigations against brand-name pharmaceutical companies throughout the country under the current statutory regime. Currently, Teva USA is a defendant in more than 40 such ANDA litigations.

As an innovator of patented, research-based pharmaceuticals, every year Teva also files hundreds of its own patent applications in the Patent and Trademark Office in order to protect its significant investment in research and development. Teva currently owns over 200 issued U.S. patents and have several hundred more patent applications pending in the Patent and Trademark Office.

Needless to say, Teva has a keen interest in any amendments to the patent statute because any changes could have a profound impact on Teva's business and on the public's access to affordable medicines.

SUMMARY

The U.S. patent system is a very important element in the economic engine which has made the U.S. the most technically advanced society in the world. The proposed changes suggested are so large, and affect so many portions of the current patent statute, that it is simply is impossible to predict how all the changes will affect each other and how the rights of the public as a whole will be affected . The law of unintended consequences is bound to come into play. Teva suggests that it is better to make changes in small bits and then consider later whether additional broad changes are really necessary. At the very least, such sweeping changes should not be made without a very detailed consideration of exactly what the problem actually is, what an appropriate correction would be and how the proposed correction will effect the public as a whole. The rationale for the sweeping changes is anecdotal only and largely based on purported problems in litigation. The overall effect on the public has not been adequately considered. Teva believes that to the extent there are problems with the current statute, they can be fixed by remedies more narrowly tailored to address specific problems.

In this submission, Teva comments only on four specific proposed amendments about which it is particularly concerned. These specific changes to the patent statute in the bill will effect unnecessary and significant changes that will detrimentally affect the public by upsetting the existing balance between the rights of the patent holders and the rights of the public. The public bestows the patent monopoly on real inventions in exchange for a disclosure enabling the public to make and use the invention, and the inventor disclosing the best way he or she knows of practicing his or her invention. The proposed amendments will result in more protection for patented "inventions" by discouraging candor during proceedings in the Patent and Trademark Office, and by narrowing what qualifies as prior art. At the same time, the public will get a less effective disclosure in exchange. Moreover, the proposed amendments favor brand-name pharmaceutical companies at the expense of generic pharmaceutical companies and the public by failing to explicitly protect pre-approval regulatory activities of generic companies.

1. Discouraging Candor In Patent and Trademark Office Proceedings By Eviscerating the Unenforceability Defense For Inequitable Conduct

The proposed amendments will eviscerate the equitable unenforceability defense for inequitable conduct and introduce an unworkable and ineffective system within the Patent and Trademark Office for policing inequitable conduct.

By doing so, the proposed amendments will discourage honesty and candor during the prosecution of patents and permit unscrupulous patent holders to abuse the patent system and undermine competition.

2. Weakening the Invention Disclosure Requirement By Eliminating the Requirement To Disclose the Best Mode Of the Invention

By eliminating the requirement that the inventor disclose the best mode of carrying out the invention, the proposed amendments will deprive the public of the information they need to practice the invention after the patent expires, and undermine the fundamental bargain on which the patent system is based.

3. Narrowing the Universe of Qualified Prior Art By Requiring Prior Art To Be "Publicly Known"

The proposed amendments will restrict certain current categories of prior art – namely, sales and public uses – to those in which the invention is "publicly known." By doing so, the proposed amendments will narrow the definition of qualifying prior art and thereby weaken the standards for patentability. This will serve to reduce, not improve, patent quality and will strengthen the patent monopoly to the detriment of the public.

4. Unfairly Singling Out Brand-Name but Not Generic Pre-Marketing Approval Activities as "Commercial Uses" For Purposes Of the First Inventor Defense To Infringement.

The proposed amendments broaden the defense to infringement based on prior commercial activities of the public ("prior user rights") generally, but specifically single out the pre-approval activities of brand-name pharmaceutical companies. By doing so, the proposed amendments unfairly favor brand-name companies at the expense of generic companies and the public. Teva NA supports the amendment in general, but contends that it does not go far enough—the amendment should treat the pre-approval activities of brand-name and generic drug companies similarly.

DISCUSSION

1. Discouraging Candor In Patent and Trademark Office Proceedings By Eviscerating the Unenforceability Defense For Inequitable Conduct

A. Current Law and Perceived Problem

As the Court stated in *Norton v. Curtiss*, 433 F.2d 779 (C.C.P.A. 1970), there must be a "relationship of trust" between patent applicants and the Patent and Trademark Office. The Office has no testing facilities of its own and therefore "must rely on applicants for many of the facts upon which its decisions are based." Therefore, the "highest standards of honesty and candor on the part of applicants in presenting such facts to the office are necessary elements in a working patent system."

The current defense of unenforceability for inequitable conduct by the patent applicant or attorney during proceedings in the Patent and Trademark Office is rooted in the courts' long-standing equitable discretion to prevent a party with "unclean hands" from obtaining relief. As the Federal Circuit stated in *Consolidated Aluminum Corp. v. Foseco Int'l, Ltd.*, 910 F.2d 804 (Fed. Cir. 1990), "'inequitable conduct' is no more than the unclean hands doctrine applied to particular conduct before the [Patent and Trademark Office]."

By raising the specter that a patent will be declared unenforceable in cases where a patentee intentionally defrauds the Patent and Trademark Office, the doctrine acts as an important deterrent which encourages candor and deters fraud and dishonesty during the prosecution of a patent application. The deterrent effect of possible unenforceability greatly enhances the quality of patents issued by motivating the applicant to disclose the most important prior art known to him or her, and thereby increasing the likelihood that the Examiner will have the most pertinent prior art to consider. This is crucial to the effective functioning of the Patent and Trademark Office, because patent prosecution is conducted *ex parte*, in secret, and without the benefit of cross-examination.

Despite the acknowledged deterrent effect, submissions to the Committee asserted that some change in handling of the inequitable defense is required because the allegation of inequitable conduct is raised as a defense in nearly every patent litigation and has become a "cancer" on the practice of patent law. Others have asserted that since the intent of the applicant must be considered in assessing

inequitable conduct, such an intent-based defense results in uncertainty as to the enforceability of issued patents.

We are aware of no empirical data that these assertions are true, nor that inequitable conduct claims were not currently properly evaluated in the district courts and in the Court of Appeals for the Federal Circuit. In our experience, and in those reported decisions where inequitable conduct has been found, the conduct has been intentional and egregious. Even if some such problems do exist, the proposed amendments are not the right solution.

B. The Inappropriate Changes

The proposed amendments will eviscerate the equitable unenforceability defense based on the patentee's inequitable conduct in obtaining its patent, and introduce an unworkable and ineffective system within the Patent and Trademark Office for policing inequitable conduct. By doing so, the proposed amendments will discourage honesty and candor during the prosecution of patents and permit unscrupulous patent holders to abuse the patent system and undermine competition.

Indeed, such a change in the patent laws would be contrary to the trend of the law in other areas, such as in the securities law, in which recently enacted laws mandate a higher duty of responsibility, more openness and more transparency in dealing with the regulatory agencies and the public. It would be incongruous for Congress now to weaken the patent statute in a way which would undoubtedly encourage less candor and openness in dealings with the Patent and Trademark Office.

The proposed amendments would radically change the existing law by prohibiting a party to a patent infringement action from pleading unenforceability for inequitable conduct as a defense until *after* the court had adjudicated at least one claim in the patent to be invalid. § 136(d)(2). After such an adjudication, a party would be permitted to amend the pleadings to assert unenforceability. § 136(d)(2)(B). The court, however, would only be able to hold a patent unenforceable where it found evidence of intentional misconduct ***attributable to the patent owner himself*** (rather than his patent agent) and that constituted fraud by reason of reliance by the Patent and Trademark Office—*i.e.*, a finding that the Patent and Trademark Office would not have issued one or more invalid claims in the patent "but for" the fraud. § 136(d)(1); § 136(d)(2)(D); § 136(d)(3)(B). Misconduct by the prosecuting attorney could not be attributed to the patent owner

unless the patent owner also violates the duty of candor and good faith. § 136(d)(3)(A).

We find three primary faults with the proposed amendments: (a) the requirement that a claim be held invalid before inequitable conduct can even be raised; (b) delegation of responsibility for determining inequitable conduct to the Patent and Trademark Office, which lacks the interest, resources, or expertise to do so; and (c) adding an additional requirement to the defense of unenforceability, by requiring proof that the patent owner directly participated in the inequitable conduct.

1. Predicate Finding of Invalidity Now Required to Even Assert Unenforceability

These proposed amendments will significantly strengthen the patent monopoly by requiring a finding that a patent claim must be invalid as a prerequisite to any finding of inequitable conduct. § 136(d)(2). This significant change in the law will effectively remove unenforceability for inequitable conduct as an independent defense and ignores the doctrine's equitable nature by coupling unenforceability to patentability.

The proposed amendments also will severely reduce the existing effective deterrent to fraud and dishonesty during proceedings in the Patent and Trademark Office by permitting unscrupulous patent applicants to fraudulently procure otherwise valid patents. For example, under the proposed amendments, a patent applicant could withhold information material to the broader claims of the patent, but not to narrower claims, such as prior art that is inside the broader claims but outside the narrower claims. Those fraudulently obtained broad claims, with the seal of the United States government on them and the weight of the Patent and Trademark Office behind them would deter the public from practicing any aspect of the broad invention for up to 20 years. But the patent owner could avoid a finding that the patent, as a whole, was unenforceable, merely by suing its competitors on only the narrow claims

The requirement that no charge of inequitable conduct can be made until a claim is held by a court to be invalid, plainly is intended not to change the procedure under which inequitable conduct is determined, but rather to eliminate the effective enforcement of misconduct before the Patent and Trademark Office. If the claim has already been held invalid, a defendant can not be liable for infringing that claim. Why would the defendant even raise the inequitable conduct issue for such a claim? While the defense could apply to other claims not yet

found invalid, to require another round of discovery and a second trial on unenforceability, particularly in a second form, would be unduly costly and would extend the ultimate resolution of the litigation for an unacceptably long period of time.

2. Why Delegate Responsibility For Determining Inequitable Conduct To The Patent And Trademark Office, Which Lacks The Interest, Resources, Or Expertise To Do So?

The proposed amendments would also radically change the existing law by delegating to the Patent and Trademark Office primary responsibility for investigating and adjudicating inequitable conduct. The amendments would require the Patent and Trademark Office to set up a special office to investigate and adjudicate inequitable conduct issues and would require the courts to refer any inequitable conduct issues to the Office for investigation. § 136(e); § 136(c)(4). Under the proposed system, the Patent and Trademark Office would have the power to seek evidence by subpoena during the investigation and would be required to make a preliminary determination regarding whether inequitable conduct had occurred. § 136(e)(2)(A); § 136(e)(2)(D). If the Office determined that inequitable conduct may have occurred, the patent owner would be able to contest the determination, in which case a hearing could be held before a panel of the Board of Patent Appeals at which the Director and the patent owner would be permitted to present evidence and argument. § 136(e)(3)(B); § 136(e)(4)(A)-(B). Ultimately, the panel of the Board would issue a final determination whether inequitable conduct had occurred. § 136(e)(4)(C). Upon such a determination, the Director would be permitted to impose a civil monetary penalty of no more than $5 million for each act of misconduct. § 136(e)(5)-(6).

This elaborate procedure for investigating and adjudicating inequitable conduct by the Patent and Trademark Office represents a significant change. The Patent and Trademark Office has publicly stated that it opposes the proposed procedure as unworkable. Several federal judges and many other commentators have echoed this view. The fundamental problem is that the Patent and Trademark Office simply does not have the resources, institutional interest, or expertise in policing inequitable conduct. Indeed, former Commissioner Mossinghoff stated that he was concerned that placing such a responsibility on the already over-worked Patent and Trademark Office would even more adversely affect the quality of patents being issued. In fact, the Patent and Trademark Office has not

investigated inequitable conduct, except in *inter partes* interferences, since 1988.[1] At that time, the Patent and Trademark Office stopped such investigations because, in ***its own opinion***, it was ill-suited to make such determinations.

From 1981 to 1988, when the Office was investigating inequitable conduct, almost one million patent applications were filed in the Patent and Trademark Office. During that time period the Patent and Trademark Office reached a final disposition regarding inequitable conduct in only 19 cases and only found that inequitable conduct had occurred in four of those. Since 1988, the Patent and Trademark Office has only made a final disposition regarding inequitable conduct in seven interference cases, none of which resulted in a finding of inequitable conduct. In short, the Office's involvement in policing inequitable conduct has been at best sporadic. In Section 2010 of the *Manual of Patent Examining and Procedure*, the Patent and Trademark Office explains that it is ill-suited to police inequitable conduct because the Office "is not the best forum in which to determine whether there was an 'intent to mislead' [because] such intent is best determined when the trier of facts can observe demeanor of witnesses subjected to cross-examination."[2]

Although the Patent and Trademark Office does not have the incentive, resources, or expertise that are necessary to enforce inequitable conduct, the public and companies accused of infringing patents do. The existing system recognizes this by permitting an accused infringer to raise unenforceability as a defense in litigation and to assume the burden of dedicating the resources necessary to prove inequitable conduct in court.

Moreover, by capping the new civil penalties for inequitable conduct at $5 million, the proposed amendments may not effectively deter inequitable conduct

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[1] Official Gazette at 1095 O.G. 16 (October 11, 1988).

[2] Section 2010 also states as follows:

> Also, it is the courts and not the Office that are in the best position to fashion an equitable remedy to fit the precise facts in those cases where inequitable conduct is established. Furthermore, inequitable conduct is not set by statute as a criteria for patentability but rather is a judicial application of the doctrine of unclean hands which is appropriate to be handled by the courts rather than by an administrative body.

for valuable patents that will generate millions if not billions of dollars of monopoly revenue over their term. Unlike the current specter of a finding of unenforceability, this penalty may simply be viewed as another potential regulatory fee or tax, subject to nothing more than a utilitarian cost-benefit analysis.

3. Direct Participation by the Patent Owner in the Inequitable Conduct Would be Required to Establish the Defense of Unenforceability

The proposed amendments will also unfairly immunize a patent owner from any consequences of inequitable conduct by the prosecuting attorney absent proof of the patent owner's own breach of duty. § 136(d)(3)(A). This will permit the applicant to hide behind the attorney and renders meaningless the agency relationship between the attorney and the applicant by which the attorney normally binds the applicant as agent.

C. Examples of Effects of Proposed Changes

Although some have criticized the existing unenforceability defense for being asserted in almost every patent case, and although the majority of applicants and attorneys properly discharge their duty of candor, there are many instances where it is highly appropriate for the court to equitably apply the doctrine because the applicant or attorney has intentionally deceived the Patent and Trademark Office about a matter that is material to the patentability of the invention. The following are some illustrative examples from the case law. **As explained below, had the proposed amendments regarding inequitable conduct been in effect at the time, the patents in the following cases may not have been declared unenforceable for inequitable conduct despite the misconduct.**

a. *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315 (Fed. Cir. 2000)

The Federal Circuit affirmed the district court's finding that three patents related to high-speed chromatography via "perfusive" chromatography, which employs a special type of particles, were unenforceable due to inequitable conduct regarding inventorship. The named inventors Afeyan, Regnier, and Dean intentionally misrepresented to the Patent and Trademark Office the relationship between themselves and Polymer Labs, with whom they worked in close collaboration. Specifically, the named inventors falsely stated that they alone discovered that that materials from Polymer Labs produced outstanding

separations, when in fact this characteristic was discovered by two individuals not listed as inventors. The named inventors also falsely stated that Regnier had "initiated" or "directed" the particle work at Polymer Labs, when in fact this assertion was flatly contradicted in a contemporaneous writing by another named inventor. In addition, at least one of the named inventors "intentionally did not disclose" the extensive collaboration with Polymer Labs personnel, and the named inventors falsely suggested that Polymer Labs was only a source of raw materials. Furthermore, the named inventors concealed the extensive exchange of data concerning the characteristics of Polymer Labs' particles used for perfusive chromatography. One named inventor expressly stated, in a contemporaneous memo, "I should think that [Polymer Labs & PerSeptive] could get a patent on the structure of [the particles] re perfusion." The Federal Circuit agreed that the incorrect inventorship was the result of a "persistent course of material misrepresentations, omissions and half-truths" to the Patent and Trademark Office, and affirmed the holding of patent unenforceability due to inequitable conduct.

Had the proposed amendments regarding inequitable conduct been in effect at the time, the three patents in this case may not have been declared unenforceable for inequitable conduct, despite the patentee's "persistent course of material misrepresentations, omissions and half-truths" to the Patent and Trademark Office, because there was no predicate finding of invalidity, as required by proposed § 136(d)(2). The claims were not invalidated for incorrect inventorship. The Federal Circuit stated that "[the fact] that inventorship of the patents was incorrect – was unnecessary to the inequitable conduct decision" because it was the patentee's "falsehoods and omissions . . . calculated to 'obfuscate the threshold issue of inventorship'" that rendered the patents unenforceable. The Court noted that "[t]he simple fact is that a patent may be valid and yet be rendered unenforceable for misuse or inequitable conduct."

b. ***Purdue Pharma L.P. v. Endo Pharms.*, 410 F.3d 690 (Fed. Cir. 2005)**

The Federal Circuit affirmed the district court's finding that three patents relating to controlled release oxycodone formulations were unenforceable due to inequitable conduct. The patentee failed to inform the Patent and Trademark Office during prosecution that the claimed "discovery" was based on "insight," with no scientific proof. The patentee repeatedly represented to the Patent and Trademark Office that it had "discovered" that its controlled release oxycodone formulations controlled pain over a four-fold range of dosages for 90% of patients, compared to an eight-fold range for other opioids. The specifications state that these results were "surprisingly discovered." However, the patentee did not have

any clinical evidence to support its claim, either at the time it was made or before the patents issued. Moreover, the patentee even submitted a declaration emphasizing the difficulty of predicting the pharmacological characteristics of opioids and cautioned that "the most meaningful therapeutic conclusions" should be based on "the results of the most adequate and well-controlled therapeutic evaluations." Yet during trial, the declarant admitted that the discovery was based on "insight" rather than clinical data, and that he "envisioned" the controlled release oxycodone produces based on personal knowledge. In light of the patentee's persistent misrepresentations that the claimed products were a "surprising discovery," the Federal Circuit affirmed the holding that the asserted patents were unenforceable for inequitable conduct.

Had the proposed amendments regarding inequitable conduct been in effect at the time, the three patents in this case may not have been declared unenforceable for inequitable conduct, despite the patentee's "deliberate decision to withhold and thus misrepresent the origin of its 'discovery' to the [Patent and Trademark Office]," because there was no predicate finding of invalidity, as required by proposed § 136(d)(2). Both the district court and the Federal Circuit based the holding of unenforceability on the patentee's repeated misrepresentations to the Patent and Trademark Office, and neither court addressed invalidity. Moreover, the Federal Circuit expressly rejected any requirement of "but for" reliance under the current law. The patentee contended that it did not commit inequitable conduct "because the examiner did not rely on its assertion[s]," and that the examiner "could have allowed the claims based on other arguments it made to distinguish [its claims]." The Federal Circuit rejected this argument, stating that "[e]ven if the examiner did not necessarily rely on Purdue's discovery of a four-fold dosage range, however, that would not be inconsistent with a finding of materiality" and inequitable conduct. Under the proposed amendments, the absence of reliance would have negated the unenforceability defense.

c. ***Pollenex Corp. v. Sunbeam-Home Comfort,***
835 F. Supp.394, 403 (N.D. Ill. 1993)

The district court declared a patent related to a back massager unenforceable for inequitable conduct. Specifically, the court found that the patentee "intentionally copied prior art products that were manufactured and marketed by the Defendants, intentionally misled the [Patent and Trademark Office] about the existence of . . . highly material prior art products during the patent application process, and then turned around and sued the Defendants for infringing its newly issued patent." Before claiming its "invention," the inventors "were aware of both the [prior art] products, and indeed had disassembled and evaluated [one product]

before conceiving their claimed invention." The court not only held the patent unenforceable for inequitable conduct, but also awarded attorney's fees to the defendants because the patentee's conduct was so egregious that it was an "extraordinary case" and that it would be "grossly unjust" for the defendants to bear their own fees and expenses.

Had the proposed amendments on inequitable conduct been in effect at the time, the patent asserted in the above case would not have been declared unenforceable, despite the patentee's "flagrant inequitable conduct," because there was no predicate finding of invalidity, as required by proposed § 136(d)(2). In that case, "[t]he defendants admitted infringement, there was no trial of the obviousness issue." Finding the claims were unenforceable, the court never reached the issue of whether they were invalid. Under the proposed amendments, without a finding of invalidity, the defendants could not have raised, and the court would not have been able to consider, the patentee's "egregious" conduct.

d. *Ferring B.V. v. Barr Labs., Inc.*, 2005 U.S. Dist. LEXIS 3597 (S.D.N.Y. 2005)

The district court declared a patent related to an oral form of desmopressin designed to be absorbed by the body through the gastrointestinal tract unenforceable for inequitable conduct. During prosecution, the applicants argued that the prior art "does not teach administration via stomach route and that peroral implies 'buccal' etc., and that one skilled in the art would not think otherwise." The examiner suggested that applicants "obtain evidence from a non-inventor" to support its understanding that the term "peroral" meant "sublingual or buccal" administration and not through the stomach. The applicant submitted four declarations in response: two by Dr. Vilhardt, and one each by Dr. Czernichow and Dr. Miller. However, the applicant failed to inform the examiner that Dr. Czernichow was a Ferring consultant and received research funding from Ferring from 1985 to 1986, and again from about 1988 to 1990. The applicant also failed to inform the examiner that Dr. Vilhardt had assigned his rights in the invention to Ferring. The court found that "the close and undisclosed long-standing associations between the declarants in this case and Ferring and Vilhardt should have been disclosed in order to avoid the foreseeable inference of fraud that logically arises from the undisputed facts of this case." The court held that the patent was unenforceable for inequitable conduct.

Had the proposed amendments regarding inequitable conduct been in effect at the time, the patent in this case may not have been declared unenforceable for inequitable conduct, despite the patentee's submission of a declaration in response

to the examiner's request for a "non-inventor" statement and concealment of the actual ties between the declarants and the patentee, because there was no predicate finding of invalidity, as required by proposed § 136(d)(2). While the patentee asserted nine claims against the defendant, the defendant only raised invalidity defenses for two claims, which were denied on summary judgment after the court found inequitable conduct.

D. Conclusion

In sum, the proposed amendments will strengthen the patent monopoly by eviscerating the important equitable unenforceability defense, which is an effective deterrent to fraud and dishonesty during *ex parte* proceedings in the Patent and Trademark Office, and by replacing it with an unworkable system that will permit unscrupulous patent applicants to fraudulently abuse the system – and all of this without any evidence that the current court procedures for punishing the potential frivolous assertion of inequitable conduct are inadequate.

2. Weakening the Invention Disclosure Requirement By Eliminating the Requirement To Disclose the Best Mode Of the Invention

The proposed amendments will eliminate the requirement that the inventor disclose the best mode of carrying out the invention. By doing so, the proposed amendments will deprive the public of the information they need to practice the invention and undermine the fundamental bargain on which the patent system is based.

A United States patent is fundamentally a bargain struck between the American public on one side and the inventor on the other. In return for disclosing the details of the invention in a public document, the inventor gains a right to exclude all others from using the patented subject matter for the term of the patent. The benefit to the public, on the other hand, is that the inventor discloses in the patent the best way of using the invention so that society can build upon this public knowledge. The public benefits by the advancement of technology based upon others being able to use the body of information set forth in patent, either at its expiration or to develop new and different technologies using the patented information as a starting point.

The best mode requirement has been a part of our patent laws since almost the founding of the Republic. It is not an overstatement to say that this requirement is a large part of the reason for United States' technological success.

From the inventor's perspective, the best mode for making and using the invention is the real heart of the invention.

If inventors were not required to disclose the best mode of practicing their invention, they would have no motivation to, and would likely not disclose what would then be an important and valuable trade secret.. Even after the patent expired, the inventor could still maintain its secret rights in perpetuity at the expense of increasing public knowledge, thereby increasing the cost of goods to consumers and inhibiting the free flow of information. There can no doubt that removing the best mode requirement would substantially diminish the disclosure of this important information, to the detriment of the public.

A. Current Law and Perceived Problem

The existing statute requires that the inventor disclose "the best mode contemplated by the inventor of carrying out his invention" (35 U.S.C. § 112, ¶ 1). The Court of Appeals for the Federal Circuit has told us that this section serves two important goals. First, it holds the inventor to the fundamental bargain underlying the patent system by requiring that the inventor disclose to the public, in exchange for receiving the patent monopoly, the information necessary to carry out the best mode of the invention after the patent expires. Second, it ensures that an inventor does not receive patent protection while continuing to secretly exploit the best mode of the invention. In *Teleflex, Inc. v. Ficosa North America Corp.*, 299 F.3d 1313, 1330 (Fed. Cir. 2002) the Court stated that:

> The best mode requirement creates a statutory bargained-for exchange by which a patentee obtains the right to exclude others from practicing the claimed invention for a certain time period, and the public receives knowledge of the preferred embodiments for practicing the claimed invention.
>
> . . .
>
> The purpose of the best mode requirement is to restrain inventors from applying for patents while at the same time concealing from the public preferred embodiments of the inventions they have in fact conceived.

Some have criticized the best mode requirement as bringing uncertainty to litigation, since it depends on the subjective state of mind of the inventor. Others have argued that the reason for deleting the best mode requirement is that it is

widely litigated and requires extensive -- and expensive – discovery; and that since attacks on best mode are more of a threat to patents than an aid to promote disclosure, the best mode requirement should be eliminated. ***As with the inequitable conduct issue, no empirical data has been presented to support such assertions.***

B. Examples of Effects of Proposed Changes

Many times it is highly appropriate for the court to find a patent invalid because the inventor did not disclose to the public the information necessary to practice the invention and thus failed to live up to the terms of the statutory bargain. The following examples from the case law illustrate the problems that occur when the best mode requirement is violated. **Had the proposed amendment to eliminate the best mode requirement been in effect at the time, none of the patents in the following cases would have been declared invalid despite the failure to provide full disclosure to the public of the best mode of practicing the invention in return for the public's grant of monopoly.**

a. *Consolidated Aluminum Corp. v. Foseco Int'l, Ltd.*, 910 F.2d 804 (Fed. Cir. 1990)

The Federal Circuit affirmed the district court's finding that patents related to ceramic foam filters were invalid for failure to disclose the best mode. The best mode possessed by the inventors at the time of filing was a specific slurry, the "CS1-B" slurry, having known ingredients at known proportions. However, instead of disclosing the actual slurry used to make the claimed invention, the patent owner specified in Example 1 a fictitious and inoperable slurry which omitted key ingredients necessary to hold the ceramic together. The disclosed slurry was never used, while the ceramic foam reported in the examples was made with the undisclosed slurry. The Federal Circuit affirmed the district court's finding that not only did the patent owner fail to disclose the best mode, but that its intentional disclosure of a false and inoperable mode also amounted to inequitable conduct, rendering the patents unenforceable.

b. *Buehler AG v. Ocrim, S.p.A.*, 836 F. Supp. 1291 (N.D. Tex. 1992)

The district court found that a patent directed to a design in the control for a roller mill for grinding grain was invalid for failure to disclose the best mode. The best mode contemplated by the inventor at the time of filing was a two position valve, the "PXC-M121 valve." However, throughout prosecution, the patentee led

the examiner to believe that (1) the innovation involved a three position valve, as clearly distinguished from a two position valve, and (2) that the "advantages" of the claimed invention resulted from the use of a three position valve. The patentee later admitted that the data and figures in the patent were derived from the two position PXC-M121 valve, while the depictions in the patent appeared as three position valves. One inventor testified that the three position valve structure depicted in one of the figures was never built or tested. Moreover, the inventors could not testify as to how a three position valve would work in their invention. The court found that the patentee not only failed to disclose the best mode, but that it also misled the patent examiner to believe that the claimed invention incorporated a three position valve, which amounted to inequitable conduct. The court granted the defendants' motion for partial summary judgment for invalidity and unenforceability of the patent.

c. ***Nobelpharma Ab v. Implant Innovations, Inc.*, 141 F.3d 1059 (Fed. Cir. 1998)**

The Federal Circuit affirmed the district court's finding that a patent related to an element used for implantation into bone tissue was invalid for failure to disclose the best mode. The implants described in the patent were preferably made of titanium and had a network of particularly-sized and particularly-spaced "micropits," which can be as small as 10 to 300 nanometers. One of the named inventors, Dr. Branemark, authored a book (the "1977 Book") which disclosed implants having micropits. When a draft of the patent application was submitted to the patent agent, the patent agent deleted all references to the 1977 Book. Dr. Branemark later admitted that one "could consider" the procedure used to manufacture the micropitted surface a trade secret, and "it might be" that there were details "important to making" the micropitted surface not disclosed in the patent. The Federal Circuit found that when Dr. Branemark filed his patent application, he was aware that a variety of undisclosed machining parameters were critical to the production of a functional implant but failed to disclose this information. The court affirmed the district court's judgment of patent invalidity for failure to disclose the best mode.

d. ***Great Northern Corp. v. Henry Molded Products, Inc.*, 94 F.3d 1569 (Fed. Cir. 1996)**

The Federal Circuit affirmed the district court's finding that a patent directed to bar members used to support rolls of material such as cellophane or steel was invalid for failure to disclose the best mode. At the time of filing the patent application, the inventor's preferred way of making its "STAKKER" product was

to use diamond indentations on the product. The diamond-shaped indentations were needed to provide strength to the molded pulp, in part to prevent it from collapsing. The patent owner conceded that the specification made no mention of the diamonds, and therefore there was no disclosure of the best mode. The Federal Circuit affirmed district court's holding that patent was invalid for failure to disclose the best mode.

e. *Dana Corp. v. IPC Ltd. Pshp.*, 860 F.2d 415 (Fed. Cir. 1988)

The Federal Circuit affirmed the district court's finding that a patent related to valve stem seals for use in the manufacture of automobile engines was invalid for failure to disclose the best mode. The "Wilson report," which documented tests conducted by the inventors to determine which design was most effective in controlling leakage, stated that "two designs (409-111F and 409-111H) were quite acceptable at leakage control with fluoride surface treatment. Surface treatment is necessary to satisfactory performance of seal." The inventor's supervisor indicated to the patent counsel that, upon seeing a draft of the application, the inventor "raised the point that no reference was made to fluoride treated rubber" in the disclosure. However, nowhere did the specification disclose that a fluoride treatment must or even should be applied as indicated in the "Wilson report." The Federal Circuit found that the fluoride surface treatment was the best mode contemplated by the inventor at the time the application and was not disclosed in the specification, and granted the defendants' motion to declare the patent invalid.

C. Conclusions Regarding Best Mode

In sum, the proposed amendments to eliminate the best mode requirement will strengthen the patent monopoly and undermine the fundamental bargain on which the patent system is based by depriving the public of the information that they need to practice the invention after the patent expires and by permitting patent holders to enforce their patent monopoly while secretly exploiting the best mode of the invention. Congress should not rush to make such fundamental changes to the law which has been serving the U.S. public well for two centuries. There is no empirical evidence of any kind that the nation's laws need to be so drastically altered.

3. Narrowing the Universe of Qualified Prior Art By Requiring Prior Art To Be "Publicly Known"

The proposed amendments will restrict certain current categories of prior art – namely, public sales and uses – to those in which the invention is "publicly known." By doing so, the proposed amendments will narrow the definition of qualifying prior art and thereby weaken the standards for patentability. This will serve to reduce, not improve, patent quality and will strengthen the patent monopoly to the detriment of the public.

The existing statutory definition of prior art includes not only preexisting knowledge that is accessible to the general public, such as patents and literature published before the invention, but also any "public use" or commercial "sale" of the invention by anyone, including the inventor, that occurs more than one year before the inventor files the patent application. 35 U.S.C. § 102(b).

Under existing case law, such a use or sale need not have been publicly known to render the patent invalid. For example, in *Abbott Lab. v. Geneva Pharms., Inc.*, 182 F.3d 1315 (Fed. Cir. 1999), the Federal Circuit held that a patent claim on terazosin hydrochloride in anhydrous form, or "Form IV anhydrate," was invalid because of prior sales of that compound in the United States. The court rejected the patentee's argument that "the invention was not on sale because those who sold the claimed product did not know all of its characteristics." For the "on-sale bar" to apply, the sales offer need not specifically identify all the characteristics of the product, nor did the parties have to recognize the significance of all of these characteristics at the time of the offer. The main purpose of the on-sale bar "is to prohibit the withdrawal of inventions that have been placed into the public domain through commercialization," and therefore the patentee, having placed Form IV anhydrate into the public domain and profited therefrom, was not permitted to withdraw this subject matter already available to the public.

Thus, under existing case law, commercial exploitation by the inventor of the invention before the critical date is a bar to obtaining a patent even if the invention is held secret. The policy behind this rule is to encourage an inventor to file for patent protection in a timely manner once the invention is ready for patenting so that the invention is disclosed to the public as soon as possible. Judge Learned Hand of the Second Circuit Court of Appeals in New York articulated this concept in *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 520 (2d Cir. 1946), where he stated as follows:

> [I]t is a condition upon an inventor's right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy or legal monopoly.

Under the proposed amendments, prior art will have to be "publicly known" in the sense of being "reasonably and effectively accessible" to persons of "ordinary skill" in the relevant field, who must be able both to "gain access" and to "comprehend" the subject matter without "undue effort." § 102(a)(1); § 102(b)(3). This change in the law may effectively overrule the case law described above by potentially removing from the prior art uses or sales that are not publicly known but that are currently prior art. This narrowing of the universe of qualified prior art will lower the standards for patentability, strengthen the patent monopoly, and reduce, not improve, patent quality. Moreover, it may discourage inventors from timely filing patent applications and delay the publication of inventions to the detriment of the public.

4. Unfairly Singling Out Brand-Name but Not Generic Pre-Marketing Approval Activities as "Commercial Uses" For Purposes Of the First Inventor Defense To Infringement.

The proposed amendments broaden the defense to infringement based on prior commercial activities of the public ("prior user rights") generally, but specifically single out the pre-approval activities of brand-name pharmaceutical companies. By doing so, the proposed amendments unfairly favor brand-name companies at the expense of generic companies and the public. Teva NA supports the amendment in general, but contends that it does not go far enough—the amendment should treat the pre-approval activities of brand-name and generic drug companies similarly.

The existing prior inventor provisions provide a limited defense to infringement of a patented "method of doing or conducting business" where the person raising the defense actually "reduced to practice" and "commercially used" the method at least one year before the patent application was filed. 35 U.S.C. § 273.

Teva welcomes the proposed amendments to the extent that they extend the existing prior inventor provisions to all patents, not just business method patents. § 273(b). However, Teva is concerned with the provision that deems activities during the regulatory review period by pharmaceutical companies submitting new

drug applications (NDA) to be "commercial use," but which does not similarly deem pre-approval activities by pharmaceutical companies submitting abbreviated new drug applications (ANDA) to be "commercial use." § 273(b). This unfairly favors brand-name pharmaceutical companies to the detriment of generic pharmaceutical companies and the public. The proposed amendments should be revised such that the pre-approval activities of generic drug manufacturers, like brand-name manufacturers, are deemed to be "commercial use."

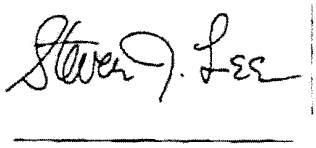
CONCLUSION

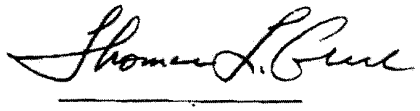
In sum, Teva NA is concerned that certain proposed amendments to the patent statute in the bill are unnecessary, and will adversely affect the public by upsetting the existing balance between the rights of patent holders and the rights of the public.

Teva NA disagrees that the existing unenforceability defense and best mode requirement introduce uncertainty into the adjudication of patents, by incorporating subjective standards for intent and the inventor's personal knowledge, respectively. Teva NA submits that any such uncertainty is a small price to pay for the resulting benefit to the public which arises from deterring dishonesty and fraud during prosecution and from holding inventors to the fundamental bargain underlying the patent system by requiring disclosure to the public, in exchange for receiving the patent monopoly, of the information necessary to carry out the best mode of the invention after the patent expires. Although the patent system would be simpler without these requirements, it would not be better, because the public would be saddled with more patents obtained by fraud and often would be denied the full benefits of disclosure. Improving quality, not simplicity, should be the overriding goal of any changes to the current patent system.

* * *

Teva NA would like to thank the Subcommittee for the opportunity to comment on the proposed amendments to the patent statute. Teva NA looks forward to providing any additional assistance that Congress may request.





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